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No. 12665

265-8

United States
Court of Appeals
for the Ninth Circuit.

12-20-50 - 12-26-50

UNITED STATES OF AMERICA,
Appellant,

vs.

EL-O-PATHIC PHARMACY, MARTIN A.
CLEMENS, HUDSON PRODUCTS COM-
PANY, MAYWOOD PHARMACAL COM-
PANY and ALLEN H. PARKINSON,
Appellees.

Transcript of Record
In Two Volumes
Volume I
(Pages 1 to 462)

Appeal from the United States District Court,
Southern District of California,
Central Division.

FILED

DEC - 9 1950

No. 12665

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Court of Appeals**
for the Ninth Circuit.

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Appellant,

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[Clerk's Note: When deemed likely to be of an important nature, errors or doubtful matters appearing in the original certified record are printed literally in *italic*; and, likewise, cancelled matter appearing in the original certified record is printed and cancelled herein accordingly. When possible, an omission from the text is indicated by printing in *italic* the two words between which the omission seems to occur.]

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In the United States District Court for the
Southern District of California, Central Division
Civil Action No. 10266-PH

UNITED STATES OF AMERICA,
Plaintiff,

vs.

EL-O-PATHIC PHARMACY, a Corporation, and
MARTIN A. CLEMENS, an Individual,
Defendants.

COMPLAINT FOR INJUNCTION

[21 U.S.C. 332(a), 331(a) and (k), 352(a),
352(f)(1) and (2), 352(j)]

United States of America, plaintiff herein, by
and through James M. Carter, United States
Attorney for the Southern District of California,
Central Division, respectfully represents to this
Honorable Court as follows:

1. This proceeding is brought under section
302(a) of the Federal Food, Drug, and Cosmetic
Act [21 U.S.C. 332(a)], hereinafter referred to as
the "Act," specifically vesting jurisdiction in the
several United States District Courts to restrain
violations of section 301 of said Act [21 U.S.C.
331] as hereinafter appears more fully.

2. The defendant, El-O-Pathic Pharmacy, Inc.,
is a corporation having its principal place of busi-
ness at 1109½ No. Western Avenue, Hollywood,
California. The defendant, Martin A. Clemens,

is the manager and director of said El-O-Pathic Pharmacy, Inc., and is primarily responsible [2*] for the policies and activities of the firm.

3. Said El-O-Pathic Pharmacy, Inc., and Martin A. Clemens are distributors of certain male and female hormone drugs; the male hormone drugs consist of methyl testosterone tablets (10 milligrams and 25 milligrams) and methyl testosterone in linguet form (5 milligrams and 10 milligrams); the female hormone drugs consist of various preparations containing alpha-estradiol (ranging from .01 milligrams to .5 milligrams).

4. Said male and female hormone drugs are manufactured by Ciba Pharmaceutical Products, Inc., Summit, New Jersey, by Roche-Organon, Inc., Nutley, New Jersey, and by Schering Corporation, Bloomfield, New Jersey, and are shipped in interstate commerce by said manufacturers to said defendants. During the interstate and intrastate journeys of said drugs from the manufacturers to the defendants, the labeling of each such drug bears the legend: "Caution: To be dispensed only by or on the prescription of a physician."

5. In the sale and distribution of said drugs, defendants do not require a physicians prescription. Instead, defendants repackaged and relabeled said drugs and offer them for sale without a physician's prescription. For example, the 10 milli-

* Page numbering appearing at foot of page of original Certified Transcript of Record.

gram methyl testosterone linguets are relabeled as follows:

El-O-Pathic Hormones
50 Tablets
Each Tablet Contains
10 Mg. Methyl Testosterone

Suggested Dosage: One tablet upon arising before breakfast or one tablet shortly before retiring. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from three to six months, under supervision of a physician.

Directions: For use by adult males deficient in male hormone [3] when small dosages of male hormone are prescribed or recommended by a physician for palliative relief of such symptoms.

Distributed by El-O-Pathic Pharmacy
1109½ No. Western Ave. Hollywood 27, Calif.
Hollywood 9-1722

(Read Side Panels)

[Side Panels]

Caution: The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate or by anyone with cardiovascular disease, defects of spermatogenesis, sterility whether absolute or partial, or debilitation due to disease. Caution

should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed.

It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted, since testosterone will not aid or relieve symptoms not associated with male hormone deficiency. Children and young adults must not use except under constant direct supervision of a physician.

6. In window and store displays and in newspaper advertising, defendants represent and suggest that said drugs are efficacious in alleviating a variety of disease conditions, especially those allegedly relating to sexual impotence in men and to change of life in women.

7. Said defendants are also circularizing former customers offering the methyl testosterone linguets in quantities up to 1000, to be purchased before said defendants' "Mail Order Department" is [4] discontinued on September 15, 1949.

8. Defendants violate section 301(k) of the Act [21 U.S.C. 331(k)] by causing the 10-milligram methyl testosterone linguets to become misbranded while held for sale after shipment in interstate commerce, in the following respects:

(a) Within the meaning of section 502(f) (1) of the Act [21 U.S.C. 352 (f)(1)] in that the printed matter which defendants cause to

become the labeling of said linguets fails to bear adequate directions for use since it fails to state all of the diseases or conditions of the body for which the drug is intended.

(b) Within the meaning of section 502(f) (2) of the Act [21 U.S.C. 352(f)(2)] in that the printed matter which defendants cause to become the labeling of said linguets fails to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, in such manner and form as are necessary for the protection of the user, since the technical medical terminology in which the cautionary statement on the labeling is couched is inadequate to warn the ordinary lay user that its use may accelerate the malignant growth of a cancer of the prostate gland or may cause sterility.

(c) Within the meaning of section 502(j) of the Act [21 U.S.C. 352(j)] in that said linguets are dangerous to health when used in the dosage and with the frequency prescribed, recommended and suggested in the printed matter which defendants cause to become the labeling of said drug, since such use of the drug may result in sterility, and may accelerate the malignant growth of a cancer of the prostate gland. [5]

9. Defendants further violate section 301(a) of the Act [21 U.S.C. 331(a)] by causing the introduc-

tion into interstate commerce of said 10-milligram methyl testosterone linguets misbranded in the same respects as described in paragraph 8(a), (b) and (c) above.

10. With respect to the 5-milligram methyl testosterone linguets, labeled exactly as described in paragraph 5 except that 5 mg. is substituted for 10 mg., defendants violate section 301(k) of the Act [21 U.S.C. 331(k)] by causing said linguets to become misbranded while held for sale after shipment in interstate commerce, in the following respects:

(a) Within the meaning of section 502(a) of the Act [21 U.S.C. 352(a)] in that the printed matter which defendants cause to become the labeling of said linguets is false and misleading since it represents and suggests that one tablet daily is efficacious for use in the treatment of male hormone deficiency, whereas one tablet daily would be entirely ineffective for that purpose.

(b) Within the meaning of section 502(f) (1) of the Act [21 U.S.C. 352(f)(1)] in that the printed matter which defendants cause to become the labeling of said linguets fails to bear adequate directions for use since it fails to state all of the diseases or conditions of the body for which the drug is intended.

(c) Within the meaning of section 502(f) (2) of the Act [21 U.S.C. 352(f)(2)] in that the printed matter which defendants cause to become the labeling of said linguets fails to bear adequate warnings against use in those

pathological conditions where its use may be dangerous to health, in such manner and form as are necessary for the protection of the user, since the technical medical terminology in which the cautionary statement on the labeling is couched is inadequate to warn the ordinary lay user that its use may accelerate the malignant growth of a cancer of the prostate [6] gland or may cause sterility.

11. Defendants further violate section 301(a) of the Act [21 U.S.C. 331(a)] by causing the introduction into interstate commerce of said 5-milligram methyl testosterone linguets misbranded in the same respects as described in paragraph 10(a), (b), and (c) above.

12. With respect to the methyl testosterone tablets, it is likely that the defendants will cause the same violations of section 301(a) and (k) of the Act [21 U.S.C. 331(a) and (k)] as they are causing with respect to the methyl testosterone linguets (as described in paragraphs 8 and 9 above), since the tablets have the same dangerous potentialities as the linguets; and since the defendants have in the past sold these products freely, without a physician's prescription, and without adequate warnings.

13. With respect to the alpha-estradiol preparations, it is likely that the defendants will cause the same violation of section 301(a) and (k) of the Act [21 U.S.C. 331(a) and (k)] as they are causing with respect to the methyl testosterone linguets (as

described in paragraphs 8 and 9 above), since the unrestricted use of alpha-estradiol preparations by women may accelerate the malignant growth of cancer of the breast, cervix, and uterus, and may cause injury to the female generative system; and since the defendants have in the past sold these products freely, without a physician's prescription, and without adequate warnings.

14. In the case of *United States v. El-O-Pathic Pharmacy and Martin A. Clemens*, No. 20596-Criminal, this Court on July 13, 1949, convicted said defendants for the distribution of misbranded male and female hormones in violation of the Act. The hormones there involved included methyl testosterone linguets, methyl testosterone tablets, and an alpha-estradiol preparation. In announcing judgment, the Court stated it was convinced beyond a reasonable doubt that these hormone preparations constitute not merely a potential danger but also an actual danger to health when used indiscriminately by the lay person. The Court also stated that the therapeutic claims which defendants made for their products far exceeded the benefits that could be derived from them.

15. Within a month after the aforesaid conviction, defendants have [7] embarked upon a widespread promotion of some of the same products in essentially the same misbranded condition as were the products involved in the criminal prosecution. Defendants' revision of the labeling is merely a subterfuge by which they hope to deceive the Court and defraud the public.

16. The plaintiff is informed and believes that unless restrained by the Court, the defendants will continue to introduce and deliver for introduction into interstate commerce the said articles of drug misbranded in the manner aforesaid, and will continue to do those acts, while holding said drugs for sale after shipment in interstate commerce, which result in misbranding in the manner aforesaid.

Wherefore, plaintiff prays:

That the defendants, El-O-Pathic Pharmacy, Inc., a corporation and Martin A. Clemens, an individual, and each and all of their officers, agents, servants, employees, and attorneys, and all persons in active concert or participation with any of them, be perpetually enjoined from directly or indirectly causing to be introduced or delivered for introduction into interstate commerce, in violation of section 301(a) of the Act [21 U.S.C. 331(a)] the articles of drug, hereinbefore described, or any similar articles, misbranded within the meaning of sections 502(a), 502 (f)(1) or (2), or 502(j) of the Act [21 U.S.C. 352(a), 352 (f)(1) or (2), or 352(j)];

That the said defendants and all other persons hereinabove enumerated be further perpetually enjoined from directly or indirectly causing any act to be done with respect to the articles of drug, hereinbefore described, or any similar articles, while said drugs are held for sale after shipment in interstate commerce, in violation of section

301(k) of the Act [21 U.S.C. 331(k)], which causes any of said drugs to become misbranded within the meaning of sections 502(a), 502(f)(1) or (2), or 502(j) of the Act [21 U.S.C. 352(a), 352(f)(1) or (2), or 352(j)];

That a Temporary Restraining Order be granted without notice to the defendants restraining the defendants as prayed herein, since as shown by the attached affidavits immediate and irreparable injury, loss, and damage will result to the plaintiff before notice can be served and a hearing had thereon;

That at the earliest possible time during the effectiveness [8] of the Temporary Restraining Order, an order be made and entered directing the defendants to show cause, at a time and place to be designated in such order, why they should not be restrained as herein prayed during the pendency of this action; that upon the hearing of said order to show cause, a Preliminary Injunction be granted restraining the defendants as herein prayed during the pendency of this action;

That the plaintiff be given judgment for its costs herein and for such other and further relief as to the Court may seem just and proper.

/s/ JAMES M. CARTER,
United States Attorney.

[Endorsed]: Filed September 2, 1949. [9]

[Title of District Court and Cause No. 10266-PH.]

AFFIDAVIT OF
CLINTON HOBART THIENES, M.D.

United States of America,
Southern District of California—ss.

State of California,
County of Los Angeles.

Before me, Ola H. Bain, an employee of the Federal Security Agency, Food and Drug Administration, designated by the Federal Security Administrator, under authority of the Act of January 31, 1925, c. 124, sec. 1, 43 Stat. 803, and reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940, to administer or take oaths, affirmations, and affidavits, personally appeared Clinton Hobart Thienes, M.D., in the County and State aforesaid, who, being first duly sworn, deposes and says:

(1) I am a licensed physician in the State of California with the degree of Doctor of Medicine from the University of Oregon Medical School and the degree of Ph.D. in pharmacology from the Stanford University Medical School.

(2) I am Chairman of the Department of Pharmacology at the University of Southern California Medical School.

(3) Pharmacology is the science of the study and action of drug and other products in the treatment of disease.

(4) I have been engaged in the private practice of internal medicine with offices at 2007 Wilshire Blvd., Los Angeles, California.

(5) The drugs, methyl testosterone linguets, methyl testosterone [10] tablets, and alpha-estradiol preparations, are highly potent and, within restricted limits, they have dramatic value in the treatment of some disease conditions. However, they do not have general widespread therapeutic value.

(6) The danger in the use of methyl testosterone linguets and methyl testosterone tablets in men lies in the fact that they may cause sterility and may accelerate the growth of cancer of the prostate gland.

(7) The danger in the use of alpha-estradiol preparations in women lies in the fact that they may accelerate the growth of cancer of the breast, cervix, and uterus, and may cause injury to the female generative system.

(8) None of these drugs should be used except upon two conditions: (a) careful diagnosis by a competent physician to determine that there is actual need for the drugs, and (b) examination by a competent physician before administration and at regular intervals during administration, to detect the possibility of cancerous growth. In addition, men given methyl testosterone should be warned as to the danger that sterility may result from continued use, and women given alpha-estradiol should

be examined at regular intervals to detect the possibility of injury to the female generative system.

(9) These drugs should not be distributed to lay persons without a physician's prescription because lay persons are not competent to diagnose the hormone deficiency condition which indicates the need for such a drug, nor is the lay person competent to diagnose the presence of cancerous growth which would contraindicate the use of such a drug.

(10) Distribution of these drugs to lay persons without a physician's prescription is a menace and a hazard to the public, and through their insidious effects they may cause widespread suffering and death.

/s/ CLINTON HOBART THIENES,
M.D.

Subscribed and sworn to before me at Los Angeles, California, this 2nd day of September, 1949.

/s/ OLA H. BAIN,
Employee of the Federal Security Agency, designated under Act of January 31, 1925, and Reorganization Plan IV effective June 30, 1940.

[Endorsed]: Filed September 2, 1949. [11]

[Title of District Court and Cause No. 10266-PH.]

AFFIDAVIT OF ELMER BELT, M.D.

United States of America,
Southern District of California—ss.

State of California,
County of Los Angeles.

Before me, Ola H. Bain, an employee of the Federal Security Agency, Food and Drug Administration, designated by the Federal Security Administrator, under authority of the Act of January 31, 1925, c. 124, sec. 1, 43 Stat. 803, and Reorganization Plan No. IV, secs. 12-15, effective June 30, 1940, to administer or take oaths, affirmations, and affidavits, personally appeared Elmer Belt, M.D., in the County and State aforesaid, who, being first duly sworn, deposes and says:

(1) I am a licensed physician in the State of California with the degree of Doctor of Medicine from the University of California, in 1920.

(2) I did post-graduate work in Urology at the University of California and at Harvard University.

(3) I have specialized in the practice of urology since 1922. I have observed over 1000 cases of cancer of the prostate. I have published a number of scientific papers and books on diseases of the genito-urinary tract.

(4) Urology is that branch of medicine that deals with the male urinary and generative system, and the female urinary system.

(5) I am a member of the California State Board of Health. [12]

(6) The drugs, methyl testosterone linguets, methyl testosterone tablets, and alpha-estradiol preparations, are highly potent and, within restricted limits, they have dramatic value in the treatment of some disease conditions. However, they do not have general widespread therapeutic value.

(7) The danger in the use of methyl testosterone linguets and methyl testosterone tablets in men lies in the fact that they may cause sterility and may accelerate the growth of cancer in the prostate gland. It is estimated from post-mortem investigations that up to one-third of the men over 50 have a dormant cancerous growth in the prostate that may always remain dormant. However, the administration of methyl testosterone linguets or tablets greatly enhances the likelihood that such dormant cancerous growth will flare up into activity and endanger the health and life of the individual.

(8) None of these drugs should be used except upon two conditions: (a) careful diagnosis by a competent physician to determine that there is actual need for the drugs, and (b) examination by a competent physician before administration and at regular intervals during administration, to detect the possibility of cancerous growth. In addition, men given methyl testosterone should be warned as to the danger that sterility may result from continued use.

(9) These drugs should not be distributed to lay persons without a physician's prescription because lay persons are not competent to diagnose the hormone deficiency condition which indicates the need for such a drug, nor is the lay person competent to diagnose the presence of cancerous growth which would contraindicate the use of such a drug.

(10) Distribution of these drugs to lay persons without a physician's prescription is a menace and a hazard to the public, and through their insidious effects they may cause widespread suffering and death.

(11) The administration of 5 milligrams of methyl testosterone linguets daily is wholly worthless in the treatment of male hormone deficiency because this amount of testosterone is therapeutically insignificant.

(12) The administration of 10 milligrams of methyl testosterone linguets daily subjects the lay purchaser and user to all of the hazards above described. [13]

/s/ ELMER BELT, M.D.

Subscribed and sworn to before me at Los Angeles, California, this 2nd day of September, 1949.

/s/ OLA H. BAIN,

Employee of the Federal Security Agency, designated under Act of January 31, 1925, and Reorganization Plan IV effective June 30, 1940.

[Endorsed]: Filed September 2, 1949. [14]

[Title of District Court and Cause No. 10266-PH.]

AFFIDAVIT OF IAN MacDONALD, M.D.

United States of America,
Southern District of California—ss.

State of California,
County of Los Angeles.

Before me, Ola H. Bain, an employee of the Federal Security Agency, Food and Drug Administration, designated by the Federal Security Administrator, under authority of the Act of January 31, 1925, c. 124, sec. 1, 43 Stat. 803, and Reorganization Plan No. IV, secs. 12-15, effective June 30, 1940, to administer or take oaths, affirmations, and affidavits, personally appeared Ian MacDonald, M.D., in the County and State aforesaid, who being first duly sworn, deposes and says:

(1) I am a licensed physician in the State of California with the degree of Doctor of Medicine from McGill University in 1928.

(2) I have had 6½ years of post-graduate training in surgery and surgical pathology.

(3) I am a member of the Cancer Committee of the American College of Surgeons, and am one of 45 collaborators working under the Therapeutic Trials Committee investigating the treatment of cancer.

(4) I am coordinator of cancer teaching at the University of Southern California.

(5) I specialize in the treatment of cancer and allied diseases. I have diagnosed and treated approximately 1000 cases of cancer of the breast [15] in women and have reviewed the histories of about 2700 other cases of cancer of the breast.

(6) The drugs, methyl testosterone linguets, methyl testosterone tablets, and alpha-estradiol preparations, are highly potent and, within restricted limits, they have dramatic value in the treatment of some disease conditions. However, they do not have general widespread therapeutic value.

(7) The danger in the use of alpha-estradiol preparations in women lies in the fact that they may accelerate the growth of cancer of the breast, cervix, and uterus, and may cause injury to the female generative system.

(8) None of these drugs should be used except upon two conditions: (a) careful diagnosis by a competent physician to determine that there is actual need for the drugs, and (b) examination by a competent physician before administration and at regular intervals during administration, to detect the possibility of cancerous growth.

(9) These drugs should not be distributed to lay persons without a physician's prescription because lay persons are not competent to diagnose the hormone deficiency condition which indicates the need for such a drug, nor is the lay person competent to diagnose the presence of cancerous

growth which would contraindicate the use of such a drug.

(10) Distribution of these drugs to lay persons without a physician's prescription is a menace and a hazard to the public, and through their insidious effects they may cause widespread suffering and death.

/s/ IAN MacDONALD, M.D.

Subscribed and sworn to before me at Los Angeles, California, this 2nd day of September, 1949.

/s/ OLA H. BAIN,

Employee of the Federal Security Agency, designated under Act of January 31, 1925, and Reorganization Plan IV effective June 30, 1940.

[Endorsed]: Filed September 2, 1949. [16]

[Title of District Court and Cause No. 10266-PH.]

AFFIDAVIT OF ROBERT S. ROE

United States of America,
Southern District of California—ss.

Robert S. Roe, being first duly sworn, deposes and says that he is Chief, Los Angeles District, Food and Drug Administration, Federal Security Agency, and that the following facts and documents are derived from his personal knowledge and from the official records of the Food and Drug Administration in his possession:

(1) On July 13, 1949, the El-O-Pathic Pharmacy, 1109 $\frac{1}{2}$ North Western Avenue, Hollywood,

California, and its manager and director, Martin A. Clemens, were convicted in this Court of violating the Federal Food, Drug, and Cosmetic Act. (No. 20596-Criminal). The substance of the charges upon which defendants were convicted was the indiscriminate sale of dangerous drugs for lay use together with the making of extravagant therapeutic claims for those drugs. The drugs involved in that case were male and female sex hormone preparations including methyl testosterone linguets, methyl testosterone tablets, and alpha-estradiol preparations.

(2) El-O-Pathic Pharmacy and Martin A. Clemens continue to obtain these drugs from manufacturers in New Jersey. Each such drug when shipped interstate from the manufacturer to El-O-Pathic Pharmacy and Martin A. Clemens is labeled with a prescription legend, namely, "Caution: To be dispensed only by or on the prescription of a physician." The practice of these defendants [20] has been to promote large scale distribution of these drugs by creating the impression through labeling and newspaper advertising that such drugs have miraculous powers of sexual rejuvenation for men over 40, and that they will alleviate disease conditions in women caused by change of life. Said defendants do not require a physician's prescription.

(3) The current methods of distribution adopted by the defendants with respect to methyl testosterone linguets subsequent to their conviction last

month are described in paragraphs 5, 6, and 7 of the Complaint in the instant case.

(4) Attached hereto as Exhibit A is a copy of a letter, dated July, 1947, sent to the defendants and all other distributors of its products by Roche-Organon, Inc., a manufacturer of the drugs here involved. The original of this Exhibit was introduced into evidence in the criminal trial above referred to, and identified by Martin A. Clemens as having been received and read by him in 1947. This Exhibit indicates defendants were warned two years ago as to the dangers inherent in the indiscriminate sale of these drugs to the public without a physician's prescription.

(5) Defendants are in the midst of unloading a large quantity of these drugs without prescription upon the public. Defendants are thereby now causing immediate and irreparable injury, loss, and damage to the public for the reasons stated in the medical affidavits which accompany this affidavit.

/s/ ROBERT S. ROE,
Chief, Los Angeles District, Food and Drug Administration.

Subscribed and sworn to before me, this 2nd day of September, 1949.

EDMUND L. SMITH,
Clerk, U. S. District Court, Southern District of California.

[Seal] By /s/ WM. R. WHITE,
Deputy. [21]

Exhibit A

(Copy)

Roche-Organon Inc.
Nutley 10, New Jersey
Hormones

July, 1947

Gentlemen:

One of our most popular dealer helps is our literature imprinting service. Demands for Roche-Organon literature bearing the name and address of the individual dealer have increased by leaps and bounds. Because of the growing popularity of this service and because a number of dealers have only recently become Roche-Organon distributors, we would like to repeat and reemphasize the salient points of this service.

As you know, it is the firm policy of Roche-Organon never to advertise its products to the laity; therefore, the literature which you request and receive is for distribution only to your physicians. In fact, all of the more recent Roche-Organon literature bears this legend: "This pamphlet has been prepared for dissemination to the medical profession exclusively."

All Roche-Organon products, with the exception of Cytora, are strictly prescription items; literature, therefore, must be kept out of the hands of your customers. You would be breaking faith with your physicians to do otherwise. In fact, you might even endanger lives, for hormones are powerful therapeutic agents which must be administered under strict medical supervision.

So pass along these facts to all your clerks: (1) Roche-Organon literature is for physicians only. (2) Keep Roche-Organon literature out of reach of your customers. (3) All Roche-Organon products (except Cytora) bear an Rx legend on their labels, and therefore may be dispensed only on a physician's prescription. (4) Don't give out literature with prescriptions for Roche-Organon products even when the patient asks for it.

Strict observance of these rules means that the professional standing of your store will rise. Your physicians will regard your store as a truly professional hormone headquarters.

Sincerely yours,

ROCHE-ORGANON INC.

NAL-GF

(Copy)

[Endorsed]: Filed September 2, 1949. [22]

[Title of District Court and Cause No. 10266-PH.]

ORDER GRANTING TEMPORARY
RESTRAINING ORDER

Plaintiff having filed a Complaint for a temporary restraining order without notice, for a preliminary injunction, and for a permanent injunction; and plaintiff having filed affidavits in support of the prayer for a temporary restraining order without notice; and the Court having con-

sidered the Complaint and supporting affidavits; and it appearing that the defendants will continue to violate the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 331(a) and (k)] unless restrained by order of this Court; and it appearing that the defendants are causing immediate and irreparable injury and damage to the public through its present and threatened distribution of hormone products in violation of the Federal Food, Drug, and Cosmetic Act since these drugs may cause sterility in men, may accelerate the growth of cancer in the prostate gland in men, may accelerate the growth of cancer of the breast, cervix, and uterus in women, and may do injury to the [17] female generative system; and it appearing that the giving of notice to the defendants would unduly delay protecting the public from these dangerous drugs;

It Is Therefore Ordered that the plaintiff's prayer for a temporary restraining order without notice be and is hereby granted, and that the defendants, El-O-Pathic Pharmacy and Martin A. Clemens, and their officers, agents, servants, employees, and attorneys, and all other persons in active concert or participation with all or any one or more of them, be and they are hereby temporarily enjoined and restrained from directly or indirectly causing the introduction or delivery for introduction into interstate commerce, in any form or manner, of any methyl testosterone linguets, or any methyl testosterone tablets, or any alpha-estradiol preparations, which are misbranded as follows:

(1) 5-milligram methyl testosterone linguets whose labeling suggests that they are effective in the treatment of male hormone deficiency when one tablet is administered daily.

(2) 5-milligram or 10-milligram methyl testosterone linguets, or 10-milligram or 25-milligram methyl testosterone tablets, whose labeling fails to state all of the disease conditions for which they are offered to the public, particularly rejuvenation of sexual potency in men.

(3) 5-milligram or 10-milligram methyl testosterone linguets, or 10-milligram or 25-milligram methyl testosterone tablets, whose labeling fails to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health.

(4) 10-milligram methyl testosterone linguets, or 10-milligram or 25-milligram methyl testosterone tablets, which are dangerous to health when taken in accordance with the directions on their labeling.

(5) Alpha-estradiol preparations whose labeling fails to state all of the disease conditions for which they are offered to the public, particularly to alleviate disease conditions related to change of life in women.

(6) Alpha-estradiol preparations whose labeling fails to bear adequate warnings against use in those pathological conditions where their use [18] may be dangerous to health.

(7) Alpha-estradiol preparations which are dan-

gerous to health when taken in accordance with the directions on their labeling.

It Is Further Ordered that said defendants and all other persons hereinabove enumerated be and they are hereby temporarily enjoined and restrained from directly or indirectly causing any act to be done with respect to the articles of drug, hereinabove described, while said drugs are held for sale after shipment in interstate commerce, which results in said drugs being labeled as above prohibited.

Unless otherwise ordered by this Court, this order shall expire at 4:30 p.m., September 6, 1949.

. Dated this 2nd day of September, 1949.

/s/ JACOB WEINBERGER,
U. S. District Judge.

[Endorsed]: Filed September 2, 1949. [19]

[Title of District Court and Cause No. 10266-PH.]

ORDER TO SHOW CAUSE

Upon the Complaint and affidavits annexed hereto, and in view of the issuance by this Court of an Order Granting a Temporary Restraining Order on this date, it is this 2nd day of September, 1949, by the United States District Court for the Southern District of California, Central Division,

Ordered that the defendants, El-O-Pathic Pharmacy and Martin A. Clemens, show cause before

this Court in Dept. 3 at 10 a.m. on the 6th day of September, 1949, or as soon thereafter as counsel can be heard, why a preliminary injunction should not issue in this cause as prayed for in said Complaint; provided that copies of this Order and of the said Complaint and affidavits be served on said defendants forthwith but not later than on the 5th day of September, 1949.

/s/ JACOB WEINBERGER,

United States District Judge.

[Endorsed]: Filed September 2, 1949. [23]

[Title of District Court and Cause No. 10266-PH.]

AMENDMENT TO COMPLAINT FOR INJUNCTION

United States of America, plaintiff herein, by and through James M. Carter, United States Attorney for the Southern District of California, respectfully amends the Complaint for Injunction, heretofore filed in this proceeding, as follows, no responsive pleading to the original Complaint having as yet been served by the defendants:

(1) The caption of the Complaint is changed to add Vita Pharmacals, Inc., a corporation, as a defendant.

(2) Paragraph 2 of the Complaint, page 1, is changed to read as follows:

The defendants, El-O-Pathic Pharmacy, Inc.,

and Vita Pharmacals, Inc., are corporations having their principal place of business at 11091½ No. Western Avenue, Hollywood, California. The defendant, Martin A. Clemens, is the manager of both said corporations, and is primarily responsible for their policies and [25] activities.

(3) Delete paragraph 8(a) on page 4 of the Complaint, lines 6-11; delete paragraph 10(b) on page 5 of the Complaint, lines 16-21; and substitute the following paragraph in the place of each of these deleted paragraphs:

Within the meaning of section 502(f)(1) of the Act [21 U.S.C. 352(f)(1)] in that the labeling of said linguets fails to bear adequate directions for use in all conditions for which said linguets are prescribed, recommended, and suggested in their labeling and their advertising matter disseminated and sponsored by the defendants.

(4) The following paragraphs are added to page 6 of the Complaint, after line 21:

13(a). Defendants also cause to be introduced into interstate commerce a drug consisting of methyl testosterone combined with Vitamin B₁ in linguet form. Said drug is labeled as follows:

COPY OF CARTON LABEL
[Front Panel]

180 Tablets

Male Hormone (Methyl Testosterone)
Combined with Vitamin B₁Here
°

Directions: For use by adult males mildly deficient in male hormone when small dosages of male hormone are prescribed or recommended by a physician for palliative relief of such symptoms. Daily recommended intake of one light and one dark (higher potency) tablet provides 5 milligrams of Methyl Testosterone and 3 milligrams of Vitamin B₁ (Thiamin Hydrochloride) in a specially [26] prepared base for sublingual use.

(See instructions on back of box)

Maywood Pharmacal Company
[Back Panel]

Double-Your-Money-Back Agreement

If you use Maywood Hormones as directed and are not fully satisfied with the results you have obtained, return the box and the unused tablets to Maywood Pharmacal Company and we will cheerfully give you double your money back.

Suggested Dosage: One light tablet upon arising before breakfast, and one dark tablet shortly before retiring. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve

slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from 3 to 6 months, under supervision of a physician.

Caution: The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate or by anyone with cardiovascular disease, defects of spermatogenesis, sterility whether absolute or partial, or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed. Children and young adults must not use except under constant direct supervision of a physician. [27]

[Top Panel]

Maywood Hormones

The hormones in this package are of purest laboratory-controlled potency. Maywood Hormones may be obtained in 30, 60 and 180-tablet packages.

Maywood Pharmacal Company

[Side Panel]

It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted, since testosterone will not aid or relieve symptoms not associated with male hormone deficiency.

[Bottom Panel]

Methyl Testosterone
combined with Vitamin B₁

Maywood

Distributed by Maywood Pharmacal Company
6912 Hollywood Blvd.
Hollywood 28, Calif.

[Side Panel]

Pull out cellophane tape and tear off individual "Pocket Pak" at perforation. Each pocket contains average daily dose of one light (morning) and one dark (evening) tablet. This special package keeps your hormones sanitary and permits you to carry your daily dosage conveniently in your pocket. Tear off corner of pack to extract morning tablet, then cellophane can be folded to protect evening tablet until taken. [28]

13(b). The aforesaid drug (methyl testosterone combined with Vitamin B₁), labeled as described in paragraph 13(a), violates section 301(a) of the Act [21 U.S.C. 331(a)] in the following respects when defendants cause it to be introduced into interstate commerce:

(1) Within the meaning of section 502(a) of the Act [21 U.S.C. 352(a)] in that the labeling is false and misleading, since it represents and suggests that the suggested daily dosage is efficacious for use in the treatment of male hormone deficiency, whereas the sug-

gested daily dosage would be entirely ineffective for that purpose;

(2) Within the meaning of section 502(f)-(1) of the Act [21 U.S.C. 352(f)(1)] in that the labeling of said linguets fails to bear adequate directions for use in all conditions for which said linguets are prescribed, recommended, and suggested in their labeling and advertising matter disseminated and sponsored by the defendants.

(3) Within the meaning of section 502(f)-(2) of the Act [21 U.S.C. 352(f)(2)] in that the labeling of said linguets fails to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, in such manner and form as are necessary for the protection of the user, since the technical medical terminology in which the cautionary statement on the labeling is couched is inadequate to warn the ordinary lay user that its use may accelerate the malignant growth of cancer of the prostate gland or may cause sterility.

/s/ JAMES M. CARTER,
United States Attorney.

Affidavit of Service by Mail attached.

[Endorsed]: Filed September 20, 1949. [29]

[Title of District Court and Cause No. 10266-PH.]

CONSENT AND ORDER

It Is Hereby Stipulated by and between the plaintiff, United States of America, and the defendants, El-O-Pathic Pharmacy and Martin A. Clemens and Vita Pharmacals, Inc., through their respective counsel, that hearing on the Order to Show Cause, heretofore set for 10 a.m., on September 26, 1949, in this proceeding, be continued to 10 a.m., on October 3, 1949, or the first available date subsequent thereto, and that the Temporary Restraining Order issued by this Court on September 2, 1949, in this proceeding, shall be and remain in full force and effect until this Court rules on the plaintiff's prayer for a preliminary injunction after the hearing on said Order to Show Cause.

Dated: September 26, 1949.

JAMES M. CARTER,
United States Attorney,

CLYDE C. DOWNING,
Assistant United States
Attorney,

/s/ GEORGE E. DANIELSON,
Assistant United States
Attorney, Attorneys for
Plaintiff.

/s/ EUGENE M. ELSON,
Attorney for Defendants.

It Is So Ordered this 30th day of September, 1949.

/s/ PEIRSON M. HALL,

United States District Judge.

[Endorsed]: Filed October 3, 1949. [31]

[Title of District Court and Cause No. 10266-PH.]

ANSWER OF DEFENDANT MARTIN A.
CLEMENS, AN INDIVIDUAL, AND VITA
PHARMACALS, INC., A CORPORATION.

Defendants Martin A. Clemens, individually, and Vita Pharmacals, Inc., a corporation, by way of answer to the Complaint for Injunction filed herein and the Amendment thereto, admit, deny and allege as follows:

I.

Answering the allegations of Paragraph 2 of said Complaint, as amended, said defendants alleged that El-O-Pathic Pharmacy, Inc., sued herein as a co-defendant and a corporation, was dissolved as a corporation on or about September 7th, 1949; that dissolution proceedings were instituted on or about August 19th, 1949, and that said El-O-Pathic Pharmacy, Inc., is no longer in existence, and that all of the assets and liabilities of said corporation were purchased by defendant Vita Pharmacals, Inc., a corporation, on or about the 22nd day of August, 1949, and that [32] Vita Pharmacals, Inc., a corporation, is now and at all times since on or about August 19th, 1949, has been a corporation organ-

ized and existing under the laws of the State of California. In this connection, these answering defendants allege that defendant Martin A. Clemens is neither a director, officer or stockholder of defendant Vita Pharmacals, Inc., a corporation, but is now and at all times since on or about the date of its incorporation has been the General Manager thereof and primarily responsible for the policies and activities of said corporation, subject to the approval or disapproval of the Board of Directors thereof.

II.

Answering the allegations of Paragraph 3 of said Complaint, defendants deny that defendant Martin A. Clemens is now or at any time since on or about July 13th, 1949, has been a distributor of male or female hormone drugs as described in Paragraph 3 of said Complaint except in his capacity as General Manager aforesaid of Vita Pharmacals, Inc., a corporation, since on or about August 19th, 1949.

III.

Answering the allegations of Paragraph 4 of said Complaint, defendants admit that the male and female hormone drugs referred to in Paragraph 3 of said Complaint, to wit: methyl testosterone tablets (10-mg. and 25-mg.); methyl testosterone in linguet form (5-mg. and 10-mg.); and female hormone drugs consisting of various preparations containing alpha-estradiol (ranging from .01-mg. to .5-mg.) are manufactured by Ciba Pharmaceutical Products, Inc., of Summit, New Jersey; by Roche-

Organon, Inc., of Nutley, New Jersey; and by Shering Corporation, of Bloomfield, New Jersey; and are shipped in interstate commerce by said manufacturers to Vita Pharmacals, Inc., a corporation. Admit that during the interstate and intrastate journeys of said drugs from said manufacturers to defendant Vita Pharmacals, Inc., a [33] corporation, the labeling of each of said drugs bears the legend: "Caution: to be dispensed only by or on the prescription of a physician."

IV.

Answering the allegations of Paragraph 5 of said Complaint, defendants admit that defendant Vita Pharmacals, Inc., a corporation, and defendant Clemens, as General Manager thereof, do not require a physician's prescription; admit that defendant Vita Pharmacals, Inc., a corporation, and defendant Clemens as General Manager thereof, have, since on or about the date of incorporation of defendant Vita Pharmacals, Inc., re-packaged and re-labeled said drugs and have offered for sale, both interstate and intrastate, male hormone drugs without requiring a physician's prescription. These answering defendants deny that they have re-packaged and re-labeled said drugs and offered all of said drugs for sale without a physician's prescription as alleged in said Paragraph 5 of said Complaint, and in this connection defendants allege as follows: that from July 13th, 1949, to on or about August 19th, 1949, defendant Clemens did not sell or offer for sale in interstate commerce any of the

aforesaid drugs; that commencing on or about August 19th, 1949, as General Manager of defendant Vita Pharmacals, Inc., a corporation, said defendant Clemens and said defendant Vita Pharmacals, Inc., a corporation, did sell and offer for sale in interstate commerce, until restrained by this Court, the aforesaid male hormone drugs without requiring a physician's prescription, but said defendants have not, nor have either of them, at any time or at all since July 13th, 1949, sold, offered for sale, distributed or delivered for introduction into interstate commerce, any of the aforesaid female hormone preparations. Defendants allege that any and all male hormone drugs sold, offered for sale, distributed or delivered for introduction into interstate commerce by them or [34] either of them at any time since on or about August 19th, 1949, have been re-labeled by affixing to the container in which said drugs and each of them have been sold, offered for sale, distributed or delivered for introduction into interstate commerce, a label, a true and correct replica of which is attached hereto and marked Exhibit "A" hereto. Defendants further allege that no other labeling of any kind or character than that represented by Exhibit "A" hereto has been attached to any of said male hormone drugs, nor has any labeling other than that represented by Exhibit "A" hereto accompanied the shipment of any of said male hormone drugs in interstate commerce since on or about August 19th, 1949.

V.

Answering the allegations of Paragraph 6 of said Complaint, defendants and each of them deny generally and specifically each and every allegation contained therein.

VI.

Answering the allegations of Paragraph 7 of said Complaint, defendants admit that former customers of El-O-Pathic Pharmacy, a corporation, and former customers of Health Chemicals Co., have been circularized, offering methyl testosterone linguets in quantities up to 1000 to be purchased before the mail order department of said El-O-Pathic Pharmacy and said Health Chemicals Co. is discontinued on September 15th, 1949, and in this connection defendants allege that defendant Vita Pharmacals, Inc., a corporation, purchased from Health Chemicals Co. its mailing list of customers, and that the mailing list of the customers of El-O-Pathic Pharmacy, a corporation, was among the assets sold and transferred by said El-O-Pathic Pharmacy, a corporation, to defendant Vita Pharmacals, Inc., a corporation, on or about August 19th, 1949, and that the purpose of so circularizing former customers of El-O-Pathic Pharmacy and Health Chemicals Co. by [35] defendant Vita Pharmacals, Inc., a corporation, was to retain the customers of said organizations represented by the respective mailing lists thereof as customers of said defendant Vita Pharmacals, Inc., a corporation. A true and correct copy of the circular so addressed to former customers of El-O-Pathic Pharmacy, a corporation,

is attached hereto and marked Exhibit "B." A true and correct copy of the circular so addressed to former customers of Health Chemicals Co. is attached hereto and marked Exhibit "C."

VII.

Answering the allegations of Paragraph 8 of said Complaint, as amended, these answering defendants deny generally and specifically each and every allegation contained therein.

VIII.

Answering the allegations of Paragraph 9 of said Complaint, these answering defendants deny generally and specifically each and every allegation contained therein.

IX.

Answering the allegations of Paragraph 10 of said Complaint, these answering defendants deny generally and specifically each and every allegation contained therein.

X.

Answering the allegations of Paragraph 11 of said Complaint, these answering defendants deny generally and specifically each and every allegation contained therein.

XI.

Answering the allegations of Paragraph 12 of said Complaint, these answering Defendants admit that defendant Vita Pharmacals, Inc., a corporation, and defendant Clemens as General Manager thereof, have, since on or about August 19th, 1949,

sold the said methyl testosterone tablets and methyl testosterone linguets freely in intrastate and interstate commerce without a physician's prescription but labeled in the manner aforesaid. [36] Deny generally and specifically each and every other allegation contained in said Paragraph.

XII.

Answering the allegations of Paragraph 13 of said Complaint, these answering defendants deny generally and specifically each and every allegation contained therein.

XIII.

Answering the allegations of Paragraph 13(a) of said Complaint, as amended, defendants admit that defendant Vita Pharmacals, Inc., a corporation, and defendant Clemens as General Manager thereof, have caused to be introduced into interstate commerce a drug consisting of methyl testosterone combined with Vitamin B₁ in linguet form, and that said drug so introduced has been and is labeled in the manner and form described in said Paragraph 13(a). Said defendants attach hereto and mark as Exhibit "D," a true, correct and actual label so affixed to said product.

XIV.

Answering the allegations of Paragraph 13(b) of said Complaint, as amended, these answering defendants deny generally and specifically each and every allegation contained therein.

nothing by its action, and for such other and further relief as may be proper.

HOWLET AND ELSON,

By /s/ EUGENE M. ELSON,
Attorneys for Defendants.

Exhibit A

44-1

VITA HORMONES 100 Tablets

Each Tablet Contains 5 Mg Methyl Testosterone

SUGGESTED DOSAGE: One tablet upon arising before breakfast or one tablet shortly before retiring. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from three to six months, under supervision of a physician.

DIRECTIONS: For use by adult males deficient in male hormone when small dosages of male hormone are prescribed or recommended by a physician for palliative relief of such symptoms.

Distributed by VITA PHARMACALS, INC.
1109 1/2 No. Western Ave. Hollywood 27, Calif.
Hollywood 9-1722

(Read Side Panels)

It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted, since testosterone will not aid or relieve symptoms not associated with male hormone deficiency. Children and young adults must not use except under constant direct supervision of a physician.

CAUTION: The male hormone should not be taken by anyone with carcinoma of the prostate or urinary tract, or probably due to carcinoma of the prostate or by anyone with carcinoma of the prostate, defects of spermatogenesis, sterility, whether absolute or partial, or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed.

VITA HORMONES 100 Tablets

Each Tablet Contains 10 Mg Methyl Testosterone

SUGGESTED DOSAGE: One tablet upon arising before breakfast or one tablet shortly before retiring. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from three to six months, under supervision of a physician.

DIRECTIONS: For use by adult males deficient in male hormone when small dosages of male hormone are prescribed or recommended by a physician for palliative relief of such symptoms.

Distributed by VITA PHARMACALS, INC.
1109 1/2 No. Western Ave. Hollywood 27, Calif.
Hollywood 9-1722

(Read Side Panels)

It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted, since testosterone will not aid or relieve symptoms not associated with male hormone deficiency. Children and young adults must not use except under constant direct supervision of a physician.

CAUTION: The male hormone should not be taken by anyone with carcinoma of the prostate or urinary tract, or probably due to carcinoma of the prostate or by anyone with carcinoma of the prostate, defects of spermatogenesis, sterility, whether absolute or partial, or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed.

VITA HORMONES 100 Tablets

Each Tablet Contains ~~5~~ 25mg Methyl Testosterone

SUGGESTED DOSAGE: One tablet upon arising before breakfast or one tablet shortly before retiring. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from three to six months, under supervision of a physician.

DIRECTIONS: For use by adult males deficient in male hormone when small dosages of male hormone are prescribed or recommended by a physician for palliative relief of such symptoms.

Distributed by VITA PHARMACALS, INC.
1109 1/2 No. Western Ave. Hollywood 27, Calif.
Hollywood 9-1722

(Read Side Panels)

It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted, since testosterone will not aid or relieve symptoms not associated with male hormone deficiency. Children and young adults must not use except under constant direct supervision of a physician.

CAUTION: The male hormone should not be taken by anyone with carcinoma of the prostate or urinary tract, or probably due to carcinoma of the prostate or by anyone with carcinoma of the prostate, defects of spermatogenesis, sterility, whether absolute or partial, or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed.

Exhibit B

Special Bulletin

Dear Customer:

We are very sorry to inform you that effective September 15, 1949, the Mail Order Department of the El-O-Pathic Pharmacy will be discontinued.

We sincerely hope this notice will give you ample time to place your order for as many of our tablets as you may need for future use. Since many of our customers will be ordering in large quantities, we would suggest that you place your order without delay.

Please bear in mind that your order must be received and shipped on or before September 15, 1949, as this is absolutely the last date that shipments will be made.

We would like to take this opportunity to thank you for your past orders and for a very pleasant business relationship.

Sincerely yours,

EL-O-PATHIC PHARMACY,
1109½ No. Western Ave.,
Hollywood 27, Calif.

Health Chemicals Co.

c/o El-O-Pathic Pharmacy,

1109½ North Western Ave.

Hollywood 27, Calif.

Price List of Male Hormones

Methyl Testosterone

Regular Strength Linguets

<input type="checkbox"/>	30 Tablets	\$5.00
<input type="checkbox"/>	100 Tablets	\$13.00
<input type="checkbox"/>	250 Tablets	\$29.00
<input type="checkbox"/>	500 Tablets	\$55.00
<input type="checkbox"/>	1000 Tablets (Hospital Size)	\$95.00

Name

Address

City State

Please print name and address

☐ Cash ☐ C.O.D. ☐ Check or Money Order

Exhibit D

The hormones in this package are of purest laboratory - controlled potency. Maywood Hormones may be obtained in 30, 60 and 180-tablet packages.

MAYWOOD
PHARMACEUTICAL COMPANY

30 TABLETS

MALE HORMONE (Methyl
testosterone)
combined with **VITAMIN B₁**

DIRECTIONS: For use by adult males mildly deficient in male hormone when small dosages of male hormone are prescribed or recommended by a physician for palliative relief of such symp-

Daily recommended intake of one light and one dark (higher potency) tablet provides 5 milligrams of Methyl Testosterone and 3 milligrams of Vitamin B1 (Thiamin Hydrochloride) in a specially prepared base for sublingual use.

MAYWOOD
PHARMACEUTICAL COMPANY

CAUTION: The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate. It may be taken by anyone with cardiovascular disease, defects of spermatogenesis, sterility whether absolute or partial, or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed. Children and young adults must not use except under constant direct supervision of a physician.

**METHYL
TESTOSTERONE**
combined with
VITAMIN B₁

Duly Verified.

[Endorsed]: Filed October 24, 1949.

(Title of District Court and Cause No. 10266-PH.]

AFFIDAVIT OF EUGENE M. ELSON

State of California,
County of Los Angeles—ss.

Eugene M. Elson, being duly sworn, deposes and says:

That he is an attorney-at-law licensed to practice in all of the Courts of the State of California and before the above-entitled Court. That he was the trial counsel for the defendants in the criminal action referred to in the Affidavit of Martin A. Clemens filed herein. During said trial some gentleman whose name affiant does not recall sat at the end of the counsel table with the Government counsel advising and assisting them during the course of said trial. Your affiant spoke with this gentleman during several intermissions and he advised your affiant that he was a doctor of medicine employed by the Food and Drug Administration in [45] Washington, and that his activities and practice were devoted to the field of endocrinology. Your affiant stated to him in substance as follows:

“Isn’t it a fact that regardless of the labeling these people might devise for the sale of methyl testosterone without prescription, the Food and Drug Administration would never approve it?”

and said individual replied, in substance,

“That is right. We would never approve any

labeling for over the counter sales of methyl testosterone because it is our purpose to see that it is sold only on prescription.”

On October 17, 1949, your affiant requested and obtained from the Clerk of the above-entitled Court the file in the case of U. S. vs. Walter Kurt Max Hassenstein, No. 19,004, Criminal. At said time your affiant examined all the documents in said file and copied therefrom certain portions of the documents contained therein. Your affiant alleges that the defendant in said action was prosecuted by information charging him with a violation of Sections 352(f)(1) and 352(f)(2) of the U. S. Code, the corresponding sections of which in the Federal Food, Drug and Cosmetic Act are Sections 502(f)-(1) and 502(f)(2). Hereinafter in this affidavit reference to the aforesaid Federal Food, Drug and Cosmetic Act will be made instead of reference to Sections of the U. S. Code. In said information it was charged that the labeling attached to and accompanying the product involved in said action violated the aforesaid sections. Said information quoted said labeling as follows:

“Rx 5000

“Important

“To be used as directed by physician. Not to be used by children or when pregnant or [46] in the presence of serious diseases like diabetes, tuberculosis, cancer or when abdominal pains (stomach-ache, cramps, colic), nausea, vomiting (stomach sickness) or other symptoms of

appendicitis are present. Ampules should not be used in cases of nephritis, myocarditis and arteriosclerosis and threatened rupture of the uterus. Frequent or continued use of this preparation may result in dependence on laxatives. * * *''

It was charged in said information that Section 502(f)(1) of said action was violated by the afore-said label in that it failed to reveal the reason for using said article of drug. It was further charged that Section 502(f)(2) of said action was violated in that said "drug contained a solution of Posterior Pituitary and the statement, to wit, 'should not be used in cases of nephritis, myocarditis and arteriosclerosis' in the labeling was not adequate to warn against use of the drug in kidney disease, heart disease and hardening of the arteries; and in that the labeling of said drug bore no warning against use by persons with high blood pressure."

A Motion to Dismiss said information was filed on behalf of the defendant and in support thereof a Memorandum of Points and Authorities was filed. In opposition to the Points of Authorities of said defendant the Government filed a Memorandum of Points and Authorities. On page 2, line 20, to page 3, line 12, of the said Memorandum it was stated:

"With respect to the alleged misbranding in violation of Section 352(f)(1) (Section 502(f)-(1), Federal Food, Drug and Cosmetic Act) defendant rests his Motion to Dismiss upon the contention that nothing in that Section of the

Act requires the labeler to reveal the reason for the use of [47] the article, particularly since the labeling contained the statement that the preparation was to be 'used as directed by physician.' Plainly, if it is required that the labeling set forth the reasons or conditions for which the drug is to be used, such requirement is not fulfilled by a statement that it is to be used as directed by a physician. Moreover, such a direction is ambiguous and provides no assurance that the purchaser will consult a member of the medical profession. The regulations promulgated under Section 352(f)(1) (502(f)(1), Federal Food, Drug and Cosmetic Act) provide for an exemption of the requirement that the labeling contain adequate directions for use if, among other things, the labeling of the drug bears the statement 'Caution: To be dispensed by or on the prescription of a physician [21 Fed. Reg. (Cum. Supp.) Section 2.106(b)(4)].' Defendant has not taken advantage of this exemption but, rather, has carefully avoided it. Compliance with the requirements of the exemption would assure the direction and guidance of a physician in the use of the drug. The statement, however, placed on the drug by defendant does not, as stated, give any such assurance. Thus, the situation presented is apparently one where the drug is so dangerous in its use that the advice of a physician is ambiguously suggested, but the language

which would insure the drug's use on the instruction of a [48] physician is absent."

The said Memorandum of the Government further continued at considerable length on the theme that Section 502(f)(1) of said Act requires the labeling on a drug to state the conditions under which it is to be used. It was further contended in said Memorandum of the Government that the warning on the labeling used works unknown and "mysterious" to the average user.

In reply to said Memorandum of the Government the defendant filed a Memorandum of Points and Authorities contending that Sections 502(f)(1) and 502(f)(2) of the Act do not require "the purpose for the use of the medical preparation should be shown on the label," and on page 2, lines 1-5, further stated:

"When there is taken into consideration also the fact that the pleading sets forth that the product is to be used 'as directed by physician,' there can be no intimation that the statement was not inserted as a warning against the use of the product except as designated by the physician * * *."

Also in said Memorandum of the defendant it was stated on page 2, lines 22 to 29, as follows:

"The matter of describing cases of 'nephritis, myocarditis and arteriosclerosis' and the allegation that these diseases should be described as 'kidney, heart disease and hardening of the arteries, respectively, has no precedence in our

law. It would cause a criminal act to arise if, in the whimsy or caprice of a Government official the identical words approved by the Government official were not used, * * *"

Thereafter, the above-entitled Court rendered its opinion [49] entered in the Minutes of said Court as follows:

"Hall, J.:

"The statement on the label 'Important. To be used as directed by physician,' is in my judgment an 'adequate direction' for the use of the product. It is not to be used at all unless a physician directs it. To put more on the label would be to suggest it could be used without the direction of a physician which would be more apt to be false and misleading than the simple statement as used.

"The words 'nephritis, myocarditis, and arteriosclerosis' are dictionary words which are commonly understood to mean certain types of kidney, heart or arterial diseases. The warning that the product should not be used in such cases appearing under the word Important together with the statement, 'To be used as directed by physician,' is an 'adequate warning' sufficient to comply with the statute as to all except children, and is not false or misleading.

"As to the 'adequate warning against its use by children' I do not know how a more adequate warning could be given on a label

(b) Particulars Wherein Misbranding
than the statement 'not to be used by children.'

"The motion to dismiss is granted."

/s/ EUGENE M. ELSON.

Subscribed and sworn to before me this 21st day
of October, 1949.

[Seal] /s/ JAMES C. HYNE,

Notary Public in and for Said
County and State.

[Endorsed]: Filed October 24, 1949. [50]

[Title of District Court and Cause No. 10266-PH.]

AFFIDAVIT OF MARTIN A. CLEMENS

State of California,
County of Los Angeles—ss.

Martin A. Clemens, being duly sworn, deposes
and says:

That he makes this Affidavit in response to certain of the allegations contained in the Complaint for Injunction and Amendment thereto and the Affidavits of Robert S. Roe, Clinton Hobart Thienes, M.D.; Elmer Belt, M.D., and Ian MacDonald, M.D., all on file in the above-entitled proceeding.

That on or about March 22nd, 1949, there was filed an Information in the above-entitled Court numbered 20596, in which affiant Clemens was named as a defendant. In said Information it was charged that defendant Clemens delivered for in-

troduction into interstate commerce certain male hormone drugs and that the same were misbranded in violation of the Federal Food, Drug and [51] Cosmetic Act. The product involved in each Count of said Information involving male hormone drugs, the particulars wherein said products were therein alleged to be misbranded, together with the Sections of the Federal Food, Drug and Cosmetic Act alleged to have been violated, were as follows:

Count I.

(a) Product:

methyl testosterone tablets, 25-mg. each; oral dosage: 1 to 2 tablets daily;

(b) Particulars Wherein Misbranding
Was Alleged:

That accompanying said product in interstate commerce was a circular entitled "Male and Female Sex Hormones." Affiant attaches hereto and marks Exhibit "A" to this Affidavit a copy of the circular which accompanied said product.

(c) Violation Charged:

1. Section 502(a), Food, Drug and Cosmetic Act:
That the labeling represented and suggested that said product
 - a. would stimulate growth and development of the sex organs;
 - b. would stimulate growth and development of the male sex characteristics, such as
 - (1) distribution of hair
 - (2) muscular development
 - (3) depth of voice

- c. would correct lack of sexual power and impotence;
- d. would relieve and postpone the many conditions associated with middle age;
- e. would improve the sense of well-being; [52]
- f. constituted an adequate treatment for
 - (1) flushes
 - (2) sweats
 - (3) chills
 - (4) impaired memory
 - (5) inability to concentrate on activities and tendency to evade them
 - (6) nervousness
 - (7) general weakness and lack of physical strength

That the labeling represented and suggested that

- a. The use of said drug would result in improved physical and mental work
- b. The use of said drug would exert a tonic action resulting in renewed vigor
- c. Said drug would impart a better attitude toward social life
- d. Said drug would cause nervousness, exhaustion and melancholy to disappear in the average man in his late 40's

That said representations and suggestions were false and misleading in that

- a. Said drug would not accomplish the aforesaid purposes

2. Section 502(f)(2), Food, Drug and Cosmetic Act:

That said drug was further misbranded in that

- a. The said labeling failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health, in such manner and form as are necessary for the protection of the user, in that each tablet of said drug [53] containing 25-mg. of male hormone (methyl testosterone) and the labeling of said drug failed to warn that its use may result in sterility and its use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth;

3. Section 502(j), Food, Drug and Cosmetic Act:
That said drug was further misbranded in that

- a. it was dangerous to health when used in the dosage and with the frequency prescribed, recommended and suggested in its labeling, since each tablet of said drug contained 25-mg. of male hormone (methyl testosterone) and the use of a drug containing 25-mg. of male hormone in each tablet with the frequency prescribed, recommended and suggested in the labeling, to wit: as directed on the box labeling: "1-2 tablets daily," and as directed in the aforesaid circular: "1 tablet a day," would be dangerous to health since such use of said drug may result in sterility and such use by individuals with early and

incipient carcinoma of the prostate may result in acceleration of the malignant growth.

Count II.

(a) Product:

Same as in Count I

(b) Particulars Wherein Misbranding
Was Alleged:

Same as in Count I [54]

(c) Violation Charged:

Same as in Count I

Count IV.

(a) Product:

Same as in Count I

(b) Particulars Wherein Misbranding
Was Alleged:

Same as in Count I

(c) Violation Charged:

Same as in Count I except that there was no charge of failure to bear adequate warnings against use in certain conditions, etc., in violation of Section 502-(f)(2) of said Act.

There was a charge made under this Count (violation of Section 301(k) of said Act) which is not material here.

Count V.

(a) Product:

Same as in Count I

(b) Particulars Wherein Misbranding
Was Alleged:

Accompanying literature: it was not alleged that the circular referred to in the previous Counts, Exhibit "A" hereto, accompanied this product. The position of the government was that no literature other than the label on the immediate container of the product accompanied the shipment.

(c) Violation Charged:

1. Section 502(j), Food, Drug and Cosmetic Act, as in Count I. [55]

Count VI.

(a) Product:

Same as in Count I

(b) Particulars Wherein Misbranding
Was Alleged:

Same as in Count I

(c) Violation Charged:

1. Section 502(a), Food, Drug and Cosmetic Act, as in Count I.
2. Section 502(j), Food, Drug and Cosmetic Act, as in Count I.

It was not charged in this Count, as in Count I, that Section 502(f)(2) of said Act was violated in failing to bear adequate warnings against use in certain pathological conditions, etc., etc.

Count VII.

(a) Product:

Same as in Count I

(b) Particulars Wherein Misbranding
Was Alleged:

Accompanying literature: it was not charged that any literature, such as Exhibit "A" or otherwise, other than the labeling upon the immediate container in which the product was shipped accompanied this product.

(c) Violation Charged:

So far as is material here, Section 502(j), Food, Drug and Cosmetic Act, as in Count I.

Count VIII.

(a) Product:

Same as in Count I

(b) Particulars Wherein Misbranding
Was Alleged:

Same as in Count I [56]

(c) Violation Charged:

1. Section 502(a) of said Act, as in Count I.

2. Section 502(j) of said Act, as in Count I.

A violation of Section 502(f)(2) of said Act, as in Count I, was not charged under this Count.

Count IX.

(a) Product;

Same as Count I

(b) Particulars Wherein Misbranding
Was Alleged:

Accompanying literature: it was not alleged that

(c) Violation Charged:

1. Section 502(a) of said Act, as in Count I.
2. Section 502(f)(1) of said Act, as in Count I.
That the labeling of said drug failed to bear adequate directions for use in that it bore no directions for use.

However, it was alleged in said Count that said circular, Exhibit "A" hereto, did accompany said shipment and product, and affiant alleges that said circular was therefore part of the labeling.

3. Section 502(f)(2) of said Act, as in Count I.

Recapitulating the aforesaid charges insofar as the same are material to this litigation, the charges of the government were that the labeling of said products so shipped constituted a misbranding of said products for the following reasons:

1. That said labeling falsely represented and suggested that said products would be efficacious in the treatment of the conditions enumerated hereinbefore under the discussion as to Count I in violation of Section 502(a) of the Food, Drug and Cosmetic Act.

2. That said labeling failed to bear adequate warnings against use in those conditions where it might be dangerous to health in that the labeling failed to warn that its use might result in sterility and its use by individuals with early and incipient carcinoma of the prostate might result in acceleration of the malignant growth.

3. That said product was dangerous to health

in that 25-mg. thereof as prescribed: 1-2 tablets daily, [59] would be dangerous to health in the aforesaid respects in violation of Section 502(j) of said Food, Drug and Cosmetic Act.

At the outset of the trial of said action, said defendant Clemens took the position and maintained the same throughout that the symptoms referred to in said Exhibit "A" hereto would be relieved if the individual manifesting the same were suffering from a male hormone deficiency, and that said circular, Exhibit "A," did no more than make such a representation, and did not represent that said male hormone products would be efficacious in the treatment or relief of said symptoms though they might have been caused by some condition other than a male hormone deficiency, and at the outset of said action offered to the Court and served a copy thereof upon counsel, his argument in this respect entitled "Comparison of Information re Alleged Therapeutic Claims with Labeling Involved (the Pamphlet 'Male and Female Sex Hormones')," and said document so submitted became part of the files and records in said action.

Government Evidence in Support of the Aforesaid Charges

In support of the aforesaid charges, several medical witnesses were called by the government to testify. References to the reporter's transcript in said criminal action will hereinafter be made for convenience in the event that it should develop that

said reporter's transcript should be a part of the record in this case.

I.

Clinton A. Thienes, M.D.

So far as material to this case, said witness testified as follows: [60]

That in early cancer of the prostate, presence of cancerous growth may not be recognized, and that the administration under such circumstances of methyl testosterone would stimulate the cancerous growth and perhaps carry it to the point where it is no longer cureable. (R. T., p. 27) Assuming a man to be 50 years of age who complains of flushes, sweats, extreme nervousness, inability to concentrate, nocturia, and who goes to his doctor who is an average general practitioner, and no evidence of cancer of the prostate is diagnosed, he does not believe that the doctor would prescribe testosterone for a period of time and wait and see whether the symptoms were relieved. (R. T., p. 39-41) In his opinion, the general practitioner today, before prescribing testosterone, would want to be sure that his patient was suffering from the male climacteric, and in his opinion, the majority of general practitioners would require laboratory tests as to the secretion of hormones from the testes before prescribing testosterone.

The consensus of medical opinion is that methyl testosterone will cause sterility. (p. 54). Testosterone is dangerous unless prescribed "under the guidance of a physician." (p. 62).

Symptoms such as inability to concentrate and irritability in males of approximately 50 years of age are present in conditions other than hormone deficiency. Most of those symptoms are due to something other than such a deficiency. (p. 66). The only sure way that he knows to determine whether or not there is a hormone deficiency is by laboratory procedure—an analysis of the urine. (p. 67).

II.

Warren Nelson, M.D.

Professor of Anatomy and Endocrinology, University of Iowa. His studies have shown that injection of testosterone will result [61] in a lower production of spermatozoa and a lowered production of the hormones of the testes. (p. 79-80). This inhibition lasts for the duration of the treatment. How much beyond that it is difficult to say. (p. 82).

From his own research he cannot make any statement as to the effect on the testes—sterility—of methyl testosterone, but the concensus of opinion as he interprets it is that it will inhibit sperm cell production and production of testosterone by the interstitial cells. (p. 98).

He would be unwilling to say that 25-mg. of testosterone injected (this is testosterone propionate, not methyl testosterone, the latter being taken orally) would make the person sterile. In his opinion, it would reduce the production of spermatozoa and make the person less fertile. Sterility implies complete lack of fertility, (p. 102) and therefore the term

“sterility” as used in the Information, is used incorrectly. (p. 106).

If a person went to a doctor and the doctor prescribed testosterone, the result, so far as the inhibitory effect of testosterone on sperm production is concerned, would be the same as though the individual bought it at a store without prescription except that he is sure that the physician would have warned him that his fertility would probably be decreased, and if he treated himself, the patient wouldn't know that. (p. 107).

He believes that the average physician would so advise the patient. (p. 108).

In his opinion, the male climacteris is an unusual and rarely encountered condition. (p. 108). It is undoubtedly a procedure done in some instances to give a person methyl testosterone when he manifests symptoms of the male climacteric. It is assumed in those conditions that if the person is relieved, the individual is going through the male climacteric. However, at the University where individuals are admitted and are suspected of having the male [62] climacteric, laboratory tests are made to determine whether he properly belongs in that category or should receive other forms of therapy. (p. 108, 109). There is, however, a difference between the method employed by a doctor in his position associated with Universities or experimental institutions and the method in which the average general practitioner approaches the same problem. The economic factor of time as well as other factors enter into the approach. (p. 109, 110).

III.

Dr. Norris J. Heckel, M.D.

Professor of Urology, University of Illinois.

He uses testosterone in urology only for the treatment of men who have a deficiency of the male sex hormone. (p. 158). Such deficiency is found in endocrine disturbances best illustrated by eunuchism and by men who have been castrated or whose testes have been injured. (p. 159-160).

Hormone therapy would not correct impotence in a man in his late 40's unless it were due to a male hormone deficiency. (p. 168-169). In his opinion, if a man were suffering from a male hormone deficiency, methyl testosterone would correct lack of sexual power and impotence. Also, it would postpone the many conditions associated with middle age and improve the sense of well-being. If a man were suffering from a hormone deficiency, methyl testosterone would constitute an adequate treatment for flushes, sweats and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength. (p. 172, 174). However, there are many diseases other than a male hormone deficiency that would produce those symptoms. If a man were suffering from a male hormone deficiency, methyl testosterone would result in improved physical and mental work and would exert a tonic action resulting in renewed [63] vigor and would impart a better attitude toward social life and cause nervousness, exhaustion and melancholy to disappear. How-

ever, those symptoms are also symptoms of diseases or conditions other than a male hormone deficiency. (p. 173-175).

A male hormone deficiency is first determined by a careful history, second, a careful physical examination, and third, laboratory tests to aid in the diagnosis, such as the estimation of 17 ketosteroids in the urine, and also, by the estimation of the secretion of the gonadotropins in the urine. (p. 176). There are no objective symptoms which would enable him to correctly diagnose a male hormone deficiency. (p. 177).

Methyl testosterone will aggravate a prostatic cancer. (p. 180).

As to a patient calling on a general practitioner complaining of the several symptoms enumerated, i.e., nervousness, etc., etc., in his opinion the general practitioner would make a careful examination of the patient to see if he could find out what is producing the symptoms. He would conduct a complete physical examination from head to foot. If that produced nothing, he would probably examine the urine to see whether there was any sugar in it which might give him a clue to diabetes which would produce such symptoms. If he found no sugar, he would determine whether there was any albumin in the urine or whether the patient was suffering from Bright's Disease or some kidney disturbance. If nothing turned up then, he would take the patient's blood pressure. If that were normal and his urine negative, he would probably take a blood count to

see whether the patient was suffering from anemia. There might be some indication that the patient had a gastro-intestinal disturbance, and an x-ray picture of the tract or of the colon would be taken, or a basal metabolic test to discover whether he had some disturbance of his thyroid. If such doctor found nothing suspicious as a result of such examination, [64] he might, but he shouldn't, suggest testosterone to the patient for a period of 4 to 6 weeks to see if those symptoms were relieved. (p. 186-190).

He has never been able to make a diagnosis of the male climacteric. The only way that he can explain the vast quantity of testosterone sold is that he does not know of any doctor who has presented evidence of a definite diagnosis of that condition. (p. 191).

He has never been able to learn from talking with his colleagues or to find an article written by anyone in which they tell how to make a diagnosis of the male climacteric. (p. 193). There is no question but that in view of the hundreds of thousands of packages of testosterone sold during the year, testosterone is indicative of considerable benefit to many, many, many men. (p. 194-195). He believes from his own experience that methyl testosterone accelerates the growth of an incipient carcinoma of the prostate. (p. 197-199).

He questions whether the average family doctor who found what he believed to be, a male hormone deficiency and who examined the patient to see whether cancer was present, would try the man on testosterone to see whether he was relieved of his symptoms. The chances are 99 times out of 100 that

the general practitioner would find something specific as a reason for the patient's symptoms. (p.214).

IV.

Dr. Elmer Belt

He is a urologist and a member of the Belt Urological Group. (p. 224 & 372).

He has personally seen or treated patients who have had adverse or injurious results from the administration of the male hormone. (p. 227). He thinks that very definitely the administration [65] of testosterone influenced the growth of a prostatic cancer in a doctor of medicine who was his patient and who was 48 years of age. (p. 228). Cancer of the prostate is fairly frequent in the decade between 50 and 60—is much more frequent between 60 and 70. (p. 229). He sees a very selected group of patients who come to him because they have trouble in urinating. (p. 229). In the case of the ordinary practitioner to whom a patient goes because he wants a general physical examination, the practitioner is obligated to put his finger in the rectum and carefully feel the prostate. (p. 233, 234). He is convinced that testosterone is a stimulating factor for the growth of carcinoma of the prostate. (p. 243). But, about cancer of the prostate there are many more things about it that are unknown than are known. (p. 244). There are many instances in which methyl testosterone is very valuable. The precautions necessary to its use are tests: (1) the rectal examination; another, the level of acid phosphatase in the bloodstream, and two

other tests of recent origin, one, a test of the proteins of the blood, which shows the presence of cancer or the absence of it, and another, a blood protein test. He feels that such precautions are a prerequisite to any testosterone therapy except in groups where cancer of the prostate is not liable to occur and by that he means cases in which it is particularly valuable or the group of young individuals who show a definite endocrine deficiency in regard to testosterone and who need it in the normal process of their growth and development. (p. 246, 247). By that he is referring to boys who had their testicles blown off in the war, (p. 390) and persons suffering from hypogonadism—persons whose testicles are not performing their proper function, meaning undeveloped testicles and undeveloped genitalia—a young individual whose testicles are not up to standard in size and function. (p. 391, 392).

The acid phosphatase test, if one is set up for it, can be [66] completed in a few minutes. The 17 ketosteroids test requires approximately a week to complete, and the blood test a very short time. The general practitioner is not equipped to make either of those tests and in fact, his office is not equipped to make the 17 ketosteroids test, and he is having them made at California Institute of Technology. (p. 395). In a person who is apparently normal physically, the examination necessary to determine whether he is suffering from an endocrine deficiency might possibly be the 17 ketosteroids test. (p. 248). The examinations that he has referred to require special training. There are no objective symptoms of a male

hormone deficiency which a layman could recognize and actually use to diagnose such a condition. He might confuse almost anything with the loss of what he thought was his normal quantity of hormones. (p. 249). After a careful examination of the patient and no indications of cancer of the prostate being present, it would still be dangerous or conducive to the development of cancer of the prostate for the person to take testosterone. (p. 251-253).

In his opinion, if a man 45 to 50 years of age came to a general practitioner and stated that he was troubled with sweats, nervousness, did not remember things as he used to, couldn't concentrate on activities, had a tendency to evade them, and the doctor was of the opinion, after learning of these symptoms, that testosterone might be of benefit to the patient, the general practitioner would, before prescribing testosterone, in the first place, think—think about the problem, and if he thought about it very much he probably wouldn't prescribe testosterone for those symptoms because they do not indicate hypogonadism and it is virtually only in hypogonadism that testosterone is effective. (p. 383-384). A very careful analysis of the problem would be needed for that patient and he would be very apt to get it at the hands of an alert general practitioner. (p. 385). It would be a [67] very loose method of detecting the man's trouble for the general practitioner to prescribe testosterone to such a patient for a period of 3 to 4 weeks to see whether the man has been relieved, for if the doctor really thought about the problem, got down to business and studied it, he would be concerned first

about the psychic factors in the individual and whether he was overworked and troubled. (p. 385). Before prescribing testosterone, the general practitioner would certainly make a rectal examination and feel the prostate. As to blood or urine tests, there would be no blood tests that such doctor need do, unless he wished to do the acid and alkaline phosphatase tests. The urine test would not show him anything unless he wished to take the time to give the 17 ketosteroids test. (p. 385-386). If he really wanted to find out if the man had a hormone deficiency, he would give such a test, as well as the acid phosphatase test, for cancer of the prostate, (p. 386) and if he used testosterone, then he would see that the symptoms were not relieved. (p. 387).

The problem of hormone deficiency is the specialty of the general practitioner. The middle aged man who is tired and wornout and who has come to the doctor for some help is the general practitioner's "meat." (p. 388).

In the case of the individual who comes to the general practitioner and which doctor gives him a rectal examination and finds nothing suspicious and prescribes methyl testosterone for the patient, and the patient has the prescription filled that the doctor has given him, that patient can go back to a drugstore as often as he wishes and have that prescription refilled without going to that doctor or to any other doctor and having a new prescription made up for him each time he wants it. In fact, he doesn't have to have a prescription in the first place.

(p. 398). He can go back and have it refilled as often as he wants without even seeing another doctor. (p. 399) [68]

What he is pleading for in this case is that the requirement be made that this product, methyl testosterone, be sold only on prescription. (p. 400).

He does not think that the male has any climacteric, and he believes that most careful observers are of the same opinion. However, that is not an opinion that is universally shared by the profession. (p. 407).

If a patient comes to him referred by another doctor, he always allows the other doctor the benefit of whatever doubt might exist in his mind, and his tendency is to go on with the original treatment the other doctor has established until he can communicate with him and discuss the problem with him. (p. 436-437).

V.

Dr. Charles Huggins, M.D.

Professor of Urology, University of Chicago.

Since 1938 their work has been almost exclusively related to the male hormone and its action in normal and cancerous individuals. (p. 256-258). He does not think that a male hormone deficiency occurs in quasi-normal individuals—persons who are not hypogonads or who have been castrated. (p. 260). He denies that methyl testosterone would have any effect upon the conditions enumerated in the Information. Those symptoms are not symptoms of a person who is deficient in male hormones. (p. 272-275). Because of the toxic effects of the male hormone, he thinks that

testosterone should always be administered under the supervision of somebody with some knowledge of such matters. (p. 277). Testosterone in certain doses will certainly result in sterility to the user. (p. 279). Testosterone accelerates the growth of cancer of the prostate. (p. 281, and 286-287). As to the blood tests to determine the presence of cancer of the prostate, the ordinary practicing physician is not capable of doing such tests in his office unless he were chemically minded, but the average [69] good-sized hospital could determine it. (p. 289-291).

In his opinion, if an individual complained to a general practitioner—all around family doctor—of the symptoms referred to in the Information, some would prescribe methyl testosterone for a period of 4 to 6 weeks and see whether the symptoms were relieved without going through the elaborate tests described by him, but some doctors would not, and he thinks that very few informed physicians would prescribe it under those circumstances. (p. 292). He doesn't think that the average physician would recognize the symptoms referred to as an indication for sex hormones. The blood test he referred to can only be done in well-established hospitals. (p. 294). Listlessness, lack of memory, etc., as described in the Information, cannot be helped by the administration of male hormones even if the person were suffering from such a deficiency. He does not believe that there is such a thing as the male climacteric though there is a difference of opinion on that subject in medical circles, and there are a great many articles in which the male climacteric is discussed, but

he does not share the opinion of those investigators. (p. 303, 304). He is a professional investigator, (p. 311) and eliminating the eunuchoids, castrates and women, he does not think that they have prescribed testosterone in his hospital during the last 5 years. He disagrees with statements concerning the male climacteric by Dr. Hans Lisser and Robert F. Escamilla appearing in Volume 46 of "The Urologic and Cutaneous Review," page 87, February, 1942. (p. 313-315). He disagrees with statements of Dr. Harry Benjamin on the subject of impotence and its treatment by testosterone appearing in the "Urologic and Cutaneous Review," Volume 50, page 143, March, 1946, and with regard to the article by Dr. August A. Werner, entitled "The Male Climacteric: Additional Observations of 37 Patients," appearing in the Journal of Urology, Volume 49, page 82, June, 1943, he thinks they are [70] absurd and he is in complete disagreement with them. (p. 315-316).

Defense Evidence

So far as material to the issues before the Court in this case, the defense evidence in said criminal action was as follows:

I.

Martin A. Clemens

That he is a pharmacist licensed to practice in California and has been since 1927. That he purchased testosterone from Roche-Organon Company, Ciba Pharmaceutical Supply Company, and the Shering Corporation, and in addition thereto, received

literature from those companies. He has been selling testosterone since 1943 and no one at any time has made any complaint concerning alleged damage or injury from the use of said product. (p. 456-457). Since 1943 he has sold between four and five million tablets or about 127,000 boxes. These boxes were in sizes of 15, 30, 100, and 500 tablets to a box. (p. 458-459). About 20% of his sales comprised 15 tablets to a box. About 70% comprised 30 tablets to a box. About 10% comprised 100 to a box, and very few were sold in 500 tablets to a box. This latter size usually is used by dispensers. (p. 460). He has purchased testosterone from other drugstores up and down the State and had no difficulty in purchasing over the counter. (p. 476). In Los Angeles he has purchased it over the counter at 9 out of 10 drugstores that he called on. (p. 477).

The manufacturers from whom he purchased his supply furnished him with any quantity of literature that he wanted. (p. 487).

With reference to the Affidavit of Robert S. Roe on file herein, and the statement therein contained in Paragraph 4 thereof referring to Exhibit "A" attached to said Affidavit—the letter [71] of July, 1947, from Roche-Organon, Inc., affiant alleges that notwithstanding the contents of said letter, said Roche-Organon, Inc. continued to supply affiant with literature such as referred to in said letter. (p. 491). The agents of said company told him to ignore the letter; that it was merely put out to appease the medical profession, and they kept supplying him with that literature from then on, and said literature came

directly from the company's office in New Jersey. Said agents and contact men told affiant that they had to keep their product council-accepted with the medical profession—that they still had to have the outlet counsel, and to continue passing out and selling the product and the literature. (p. 525-527).

As to the allegations in said Affidavit of Robert S. Roe that affiant was warned two years ago by said letter as to the dangers inherent in the indiscriminate sale of said drugs to the public without a physician's prescription, affiant alleges that notwithstanding the contents of said letter, as aforesaid said company continued to supply him with methyl testosterone for sale to the public over the counter and without prescription, and that said company knew at all times that he was so selling said product and using the literature furnished by them to him in connection therewith. Furthermore, affiant alleges that respectable medical opinion was convincing to him that testosterone was not dangerous and that he was so advised by numerous physicians and surgeons. In addition thereto, affiant was convinced that it was possible for any individual to call on general practitioners at random, request a prescription for testosterone, and that the same would be provided without any semblance of a medical or other examination, and that by reason thereof the average general practitioner was not of the opinion that testosterone was dangerous and required the elaborate tests and examinations testified to by government witnesses in said criminal action, and [72] as more fully appears hereinafter in this Affidavit, a witness for affiant in

said criminal action did call upon 15 general practitioners at random, request and obtain prescriptions for testosterone without the semblance of a physical or any examination being made upon said individual. In addition thereto, as more fully appears hereinafter in this Affidavit, a witness for said affiant in said criminal action did call upon government witnesses Belt and Heckel and did obtain from said witnesses prescriptions for testosterone without any of the elaborate tests testified to by said witnesses as being necessary as a prerequisite for the administration of testosterone being conducted.

In addition thereto, at the conclusion of said criminal action, counsel for the government stated to the Court that he felt that because advertisements were run by affiant in the newspaper up to the day of judgment, a substantial penalty should be imposed, to which the Court replied that said defendant, affiant herein, had a right to assume himself innocent until the Court passed upon the question.

In addition thereto, the State Board of Pharmacy of the State of California, in March of 1948, held hearings throughout the State as to whether or not testosterone should be included in the list of dangerous drugs which could be sold only on prescription, and after said hearing said Board refused to place said drug upon said dangerous drug list, and the action of said Board in that connection is part of the Exhibits in the aforesaid criminal action. By reason of all of the aforesaid, affiant did not consider, prior to the Judgment of the Court in said criminal action,

that testosterone was dangerous in the respects alleged or otherwise. [73]

II.

Dr. George E. Fakehany, M.D.

Is a Doctor of Medicine, (p. 536) and prescribes testosterone on an average of once a day and has never encountered any adverse results from the use of it. (p. 542).

He prescribes testosterone to males complaining of the symptoms alleged in the Information of said criminal action. He usually prescribes a month's supply and tries it for a certain period of time to see whether the person is relieved of the symptoms complained of. (p. 547). Many individuals are relieved and some not. (p. 548). That is quite a usual procedure in the practice of medicine. It is common practice. (p. 548).

He does not submit such a patient to the tests referred to by the government medical witnesses. (p. 553-554). The symptoms referred to may or may not be caused by a hormone deficiency. (p. 582).

III.

Dr. Paul E. Travis, M.D.

Is a Doctor of Medicine (p. 596) and he prescribed testosterone for a person manifesting the symptoms referred to in the Information in such criminal action. (p. 598).

He does not nor does he know of any general practi-

tioner who submits such a patient to the tests referred to by the government medical witnesses, (p. 602) and he has never encountered any adverse results from the administration of testosterone. In his experience he has found males to suffer from a hormone deficiency. (p. 604).

IV.

Dr. William A. Swim, M.D.

Is a Doctor of Medicine and has practiced internal medicine [74] in Los Angeles since 1918. (p. 653). Was formerly a member of the Board of Medical Examiners of the State of California. (p. 654).

If a person complained to him of the symptoms described in the Information, he would take a general history, make a physical examination and prescribe testosterone, (p. 654) and has done so on many occasions and ever since there has been testosterone. There has been testosterone in commercial quantities for about the last 10 years. On many such occasions he has found the individual's symptoms to be relieved and has never encountered any adverse results. (p. 655). He is familiar with what is known as the male climacteric and the symptoms of a person suffering therefrom are those symptoms referred to in the Information. (p. 656). He does not in his practice submit the patient to the elaborate tests mentioned by the government witnesses. (p. 657).

V.

Allen H. Parkinson

Testified as a witness for the defense and stated

that on June 24th, 1949 (following the date on which government witness Dr. Elmer Belt testified on direct examination) he went to Dr. Belt's office on Wilshire Boulevard at 10:00 a.m. and asked to see one of the doctors, and was referred to a Dr. Ebert, and told him that he would like some testosterone. The doctor asked him if he had ever taken it before and he replied that he had two years ago in Salt Lake City. That a Dr. Openshaw prescribed some. (p. 696-697). He stated to said Dr. Ebert that he had trouble with diminishing of the testicles and penis, and the doctor asked him if he was taking it then, and he replied "no," but that he continued taking it at frequent intervals because it had a tonic effect and made him feel better. The doctor asked him if a 50-mg. shot of testosterone propionate would be satisfactory, and he replied that it would. He was then shown another room, and [75] in a moment a laboratory assistant entered and took a blood sample from him. Then Dr. Belt entered the room, inserted his finger in the witness' rectum, and another technician entered and injected him with testosterone. Said Dr. Belt asked him what he wanted on his prescription—how many tablets he wanted—and the witness replied that he would like 100 10-mg. linguets of methyl testosterone. Dr. Belt then said "all right" and asked him to urinate in three glasses, which he did, and asked him how he took them, and he replied that he took 3 or 4 a day, and then maybe laid off 3 or 4 days, depending on how he felt, and then resumed. Dr. Belt replied "all right" and "what did the doctor in Salt Lake City charge you?" and the witness replied

“\$5.00” and Dr. Belt replied “All right, pay the girl \$5.00 on your way out.” (p. 699-700) and said Dr. Belt wrote out a prescription for 100 10-mg. linguets of methyl testosterone. (p. 700).

In addition thereto, said witness testified that on June 30th, 1949, he called at the offices of a Dr. E. A. Gummig in Pasadena (p. 701) and received a prescription for 100 tablets of methyl testosterone linguets. At no time during his visit to the doctor's office did the doctor lay any hands on him. (p. 701o).

At this point, your affiant alleges that said Parkinson testified as aforesaid on July 7th, 1949, and that on the following day, July 8th, 1949, the said Elmer Belt was recalled to the witness stand by the government as a rebuttal witness, and testified with reference to the visit to him of said Parkinson that he did see Parkinson on June 24th, 1949; that when he went into the room where Parkinson was, he reviewed the history which the other doctor had taken, that Parkinson told him that he had been receiving a weekly maintenance dose of 50-mg. of testosterone, and in so testifying the doctor testified from notes made in his office during the course of said examination by him and by some of his employees. (p. 825-826). Parkinson asked for a prescription of [76] 10-mg. tablets or linguets of testosterone to be taken 3 times daily. He does not think he stated that he had been taking that amount. He asked for the injection and said he was going to San Francisco and wanted to have a maintenance dose to take with him. When Dr. Belt entered the room where Parkinson was, he asked him if Dr. Openshaw referred him to

them, and Parkinson said "yes." (p. 827). That two years ago his testicles and penis had begun to atrophy and he became sexually impotent. That Dr. Openshaw of Salt Lake City had been treating him with a weekly maintenance dose of 50-mg. That he had been away from Salt Lake City for three weeks and that his physician recommended that he come to them for treatment. That he was leaving for San Francisco shortly. Belt made a complete physical of Parkinson, observed his general makeup, his eyes, his pupils, his pharynx, his teeth, felt his thyroid, examined his thorax, took his blood pressure, determined his pulse rate and rhythm, felt of his abdomen, looked at his extremities, tapped his reflexes, examined external genitalia, put a finger in his rectum and examined his prostate and as a result found no contra indications for the use of testosterone. He instructed his technician to take a specimen of his blood and he had already been instructed to urinate in three glasses which he did, and that material was examined. The reason for taking the blood sample was that Parkinson said he intended to return and the doctor wanted to know whether the acid or alkaline phosphatase had changed. (p. 828-829). Before he began his examination of Parkinson, he told him that they examined people carefully who asked for testosterone or who are getting it, to be sure it isn't doing them any harm. He did not wish to undermine Doctor Openshaw's authority as the man presented himself to him as a transient under the care of another physician, and it would have been poor taste and poor policy and poor judgment as well as poor

medicine to interfere with the activities of his [77] own physician. (p. 830).

The notes of the examination from which the doctor referred disclosed the following:

“Q. Commencing with ‘Complaint,’ ‘Testosterone shots only.’ What is that (indicating)? A. History and physical.

“Q. History and physical?

“A. Wait a minute. Past history.

“Q. What is this?

“A. H. P., past history.

“Q. Oh, H. P.

“A. I guess that is history and present ailment.

“Q. H. P. I.?

“A. History of past illness.

“Q. History of past illness. It reads as follows: Two years ago, this man’s testicles and penis began to atrophy and he became sexually impotent. Dr. Openshaw of Salt Lake City has been treating him with a weekly maintenance dose of 50 milligram testosterone Neo-Hombreol. He has been away from Salt Lake City for three weeks. This physician recommended that he come here for the same shots. He will be leaving here for San Francisco shortly. Wants oral prescription for Metandren 10 milligram tablets. On the reverse side, what is this?

“A. Ear, nose and throat.

“Q. What is this up here (indicating)?

“A. Present illness, ‘P. I.,’ it looks ilke.

“Q. And something here. ‘P. I.’ the doctor

says indicates present illness. The nose, ears, eyes and throat, what is that? [78]

“A. Tonsillectomy and adenoidectomy. And then over here, ‘No venereal diseases, no surgery, general health excellent; two children.’ What is that (indicating)?

“A. ‘Daughter, age 13—and a boy aged 6 and a girl aged 4.’

“Q. Boy aged 6 and girl aged 4. What is that (indicating)?

“A. ‘Living and well.’ ”

(p. 832, line 4 to p. 833, line 15).

and your affiant alleges that nothing on said record of examination disclosed the results of the extended physical examination of said Parkinson which said Dr. Belt testified he had conducted.

With reference to the \$5.00 fee which Parkinson had testified he was charged by Dr. Belt, said Belt explained as follows:

“A. If this patient had not been referred to me from another doctor and if this were not a routine thing, a routine procedure, we would have charged him very much more for this entire procedure. Of course, \$5.00 wasn’t the total charge here. We explained to him that the laboratory test would be \$6.50, which he said he would like to have us bill him for to this false address that he gave us. This is a purely courtesy situation here. A patient comes in; he is being treated by another doctor in another city; we do our

best to oblige both the doctor and the patient by carrying on the procedure that the doctor feels is indicated. I asked him what Dr. Openshaw charged him for this treatment and he said \$5.00. As a matter of fact, \$5.00 is close to the [79] cost of 50 milligrams of testosterone propionate. I don't know exactly what the cost is to our office from the pharmacy but it is not under that. We charged him the same thing that his doctor charged him, as a matter of courtesy to that doctor, and we didn't charge him for the physical examination and for the urine analysis; nothing else except for the laboratory test." (p. 835).

VI.

Hannah Shinglman

This witness testified as a defense witness that on June 27th, 1949, she called at the Beverly Hills office of the Elmer Belt Urologic Group. (p. 739, 740). That she walked into the office and asked to see Dr. Belt and was informed by the nurse that he was not there. She then asked to see another doctor and was referred to Dr. Letourneau whose name appears on the prescription pad of the Belt Urologic Group (introduced into evidence in said case) as a member of said Group. Said doctor asked her what he could do for her and she told him that she and her husband had been in this locality 6 or 8 months and previously her husband had not been feeling well for the last few years—had been nervous, jumpy and irritable and that they figured he was going through the male

change. That a doctor in Chicago had given him some shots; that he had put him on tablets. She showed him an empty bottle which had been a container for testosterone linguets and the doctor then gave her a prescription for 100 metandren linguets, 25-mg., 1 daily, and her husband was not present at any time. (p. 745-746).

VII.

Hazen S. Parkinson

This witness testified for the defense as follows: that on Sunday, June 26th, 1949, he arrived in Chicago, and on the following [80] day called at the office of Dr. Norris J. Heckel, one of the government witnesses heretofore referred to. (p. 753-754). In a few moments the doctor came in and the witness told Dr. Heckel that he wanted to get a bottle refilled. On the label of the bottle was the language, among others: "Metandren Linguets—500." (p. 772). He showed him a prescription that he had from Dr. Openshaw for testosterone by injection, and told the doctor that he was going on a ship and wanted to take them by mouth. (p. 773). The doctor informed him that he had just returned from Los Angeles on a trial and in reply to the question from the witness "Was there anything wrong with taking them, then, that is going to do me any danger? If there is I don't want them," the doctor replied, "Oh, no, I don't know as they will do you any damage, but we don't want them sold over the counter." The doctor took a urine sample and placed his finger up the rectum of the witness, and wrote the prescription for

500 metandren methyl testosterone linguets in the witness' presence. He told the doctor he was going on a ship and that there were 3 or 4 men to a room, and every time you take a pill, someone else wants one, and he placed upon the prescription a dosage of 1 per day. About 5 or 6 minutes were consumed in this visit with the doctor. (p. 774-775). At the time of this visit the witness was 65 years of age. (p. 776).

Following this testimony, the government obtained from Dr. Heckel a letter giving his version of this visit which it was stipulated between counsel would be the testimony of said doctor if he were re-called. Said letter alleged that on June 24th, 1949, a Mr. Parkinson came to his office in Chicago and stated that he had been referred by a former patient; Parkinson said that he was 72 years of age, a sailor by occupation and gone from the country for long periods of time; that he was in Chicago as a transient; that his doctor in Salt Lake City had been giving him a prescription [81] for methyl testosterone and that he had been taking this drug under his doctor's direction for the past several years; that he was leaving the country and needed about a year's supply of testosterone and requested a prescription for a year's supply. He showed Dr. Heckel a prescription for testosterone issued by another doctor. Dr. Heckel then made a physical examination of Parkinson, which included a urine analysis and a rectal examination of the prostate and found no contraindication to the use of testosterone; he found that Parkinson's prostate was of normal size, shape and consistency, with no evidence of prostatitis; and that he then re-

newed Parkinson's prescription for methyl testosterone linguets and advised him to report to his physician at regular intervals.

During the testimony of said Parkinson, affiant herein and defendant in said action sought to elicit from said witness testimony concerning certain general practitioners called upon at random by said Parkinson during the course of said trial, from whom in each instance he obtained prescriptions for methyl testosterone without any examination being conducted. The purpose of said testimony was to dispute the testimony of government witnesses that general practitioners would not prescribe said drug without elaborate examinations to determine whether or not the individual was suffering from a male hormone deficiency or carcinoma of the prostate was indicated. Said offer of proof was refused but affiant herein alleges that he is now ready and able to prove all of the matters and things embraced in said offer of proof, and therefore alleges that said offer of proof was and is now as follows:

"I also offer to prove that Mr. Parkinson called on several doctors, on the dates mentioned on certain prescriptions, throughout parts of Los Angeles County, and talked at random; that in each instance he went into [82] the doctor's office, told the doctor that he wanted this same bottle, the one he used when he saw Dr. Heckel, refilled, and asked for a prescription; that in each instance he received a prescription for these linguets and on no occasion was anything said to Mr. Parkinson about sterility or fertility or

cancer of the prostate, nor did any of the doctors lay a hand on him, and he did not call on any doctor who turned him down on the request for a prescription.

The doctors that would be subject to Mr. Parkinson's testimony in that regard would be Dr. G. G. Ferbryck, M.D., 516 Professional Building, 117 East 8th Street, Long Beach, California, who wrote out a prescription for Metandren Linguets, one a.m. and p.m., and the date was June 29, 1949; Dr. Wayne P. Hanson, in the same building, on June 30, 1949, wrote out a prescription for 500 10-milligram Metandren Linguets, directions, one linguet daily; that he also called on Dr. George D. Stilson and Dr. Milo Ellik, together in the same office, 511 Professional Building, 117 East 8th Street, Long Beach, on June 30th, and received a prescription from Dr. Ellik for 500 Metandren Linguets, directions, as directed; that he called on Dr. Raymond W. Kelso on June 31, 1949, the doctor's address being 117 East 8th Street, Long Beach, who wrote out a prescription for 250 10-milligram Metandren Linguets, with directions, dissolve one on tongue each day; that he called on George B. Hanson, M.D., 716 Professional Building, 117 East 8th Street, Long Beach, on June 30, 1949, received a prescription for 250 Metandren Linguets, 10 milligrams, directions, one per day; that he called on Dr. H. F. Gramlich on June 30, 1949, address, 117 East 8th [83] Street, Long Beach, and received a prescription for one bottle of metandren linguets, directions, as directed; that he called on Dr. P. W. Prince of the Bishop Clinic staff, 117 East 8th Street, Long Beach,

on June 30, 1949, and received a prescription for 250 10-milligram metandren linguets, directions, I guess it is, one daily, dissolve in mouth; that he called on Dr. L. L. Wiltse, 714 Professional Building, 117 East 8th Street, Long Beach, on June 30, 1949, and received a prescription for 500 metandren linguets, directions, take as directed; that he called on Dr. Marvin R. Lauer, 829 East Compton Boulevard, Compton, California, on July 2, 1949, and received a prescription for 500 metandren linguets, 10 milligrams, directions, use as directed; that he called on Dr. Francis J. Ort, 107 North Santa Fe Avenue, Compton, California, on July 2, 1949, and received a prescription for 500 metandren linguets, directions, two daily; that he called on Dr. L. C. Lowe, 706 South Hill Street, Los Angeles, on July 1, 1949, and obtained a prescription for 500 metandren linguets, 10 milligrams, directions, as directed; that he called on Dr. Glenn E. Jones, 403 West 8th Street, Los Angeles, on July 1, 1949, and received a prescription for 500 metandren linguets, 10 milligrams, directions, one or two per day; that he called upon Dr. R. L. Byron, 1015 Chapman Building, 756 South Broadway, Los Angeles, on July 1, 1949, and received a prescription for 500 metandren linguets, 10 milligrams, directions, one as directed." (p. 764-767). [84]

The Re-Labeling of Said Products Subsequent to the
Aforesaid Judgment of Conviction

Immediately following the judgment of conviction in said criminal action, affiant consulted with legal counsel and expert counsel in other respects on the

subject of re-labeling said product so as to conform to the objections made by the government and disclosed by government evidence in said criminal action. In so doing, affiant had in mind that said government witnesses, with the exception of Dr. Charles Huggins, had testified that methyl testosterone was of great value in relieving the symptoms referred to in the Information in said criminal case provided that the individual was suffering from a male hormone deficiency; that said symptoms might, however, be caused by conditions or diseases other than a male hormone deficiency, and that only a doctor could correctly diagnose the condition.

That it was alleged in said criminal Information that the labeling there involved failed to warn the user that said product might accelerate the growth of an incipient carcinoma of the prostate and might cause sterility. Affiant alleges that in said criminal Information the term "carcinoma of the prostate" was employed as distinguished from "cancer of the prostate." Therefore, in order to meet the objections so made by the government in said criminal action to the labeling formerly employed by affiant, he discarded all of the labeling formerly employed by him, and with the assistance of counsel as aforesaid, entirely re-drafted the labeling for said product. In order to eliminate the objections that said product should not be continued over a period of time unless under the supervision of a physician in that sterility might be caused thereby, or a carcinoma of the prostate might be accelerated in growth thereby, said affiant caused to be placed upon said label, among

other things, [85] language to the effect that said product should be taken, 1 tablet upon arising before breakfast, or 1 tablet shortly before retiring, and that “the maintenance dosage can be extended from 3 to 6 months under supervision of a physician.” (Emphasis added).

In order to overcome the objections made by the government in said criminal action that an individual layman could not diagnose his need for said product, affiant caused also to be placed upon said label directions as follows:

“For use by adult males deficient in male hormone when small dosages of male hormone are prescribed or recommended by a physician, for palliative relief of such symptoms.” (Emphasis added).

As a further caution to users of said product that a physician should be consulted for the purpose of determining whether or not the symptoms manifested were the result of a male hormone deficiency, affiant caused to be added to said label the following language:

“It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted since testosterone will not aid or relieve symptoms not associated with male hormone deficiency.”

During the course of said criminal action, some witnesses for the government testified that should

testosterone be taken by young men who were desirous of stimulating their sexual desire it might result harmfully to them unless under the guidance of a physician. Therefore, in order to meet said objections, affiant caused to be placed upon said label the following:

“Children and young adults must not use except under constant direct supervision of a physician.” (Emphasis added). [86]

In order to meet the objections of the government and the testimony of witnesses produced by the government in said criminal action against the sale of said product without adequate warnings against the use thereof when carcinoma of the prostate is indicated and without adequate warnings that the use of said product might cause sterility, affiant caused to be placed on said label the following cautionary language:

“The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate, or by anyone with cardiovascular disease, defects of spermatogenesis, sterility whether absolute or partial, or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed. (Emphasis added.)

A true and correct copy of each of the labels appearing upon all of said products sold and distributed by defendants herein since the date of the judgment

in said criminal action is attached hereto and marked Exhibit "B."

In response to the allegations contained in the Complaint for Injunction in this action and the Affidavits filed in support thereof, that 5-mg. of methyl testosterone have no therapeutic value, affiant alleges that the United States Pharmacopoeia lists the dosage of methyl testosterone as follows:

"Average dose, sublingual, 5 milligrams."

That the American Medical Association, in the 14th Edition of "Useful Drugs, 1947" lists under methyl testosterone the following:

"Dosage: average dose, sublingual, 5 milligrams." That also, the American Medical Association, in its publication [87] entitled "Epitome of the Pharmacopoeia of the United States" and the "National Formulary, 8th Edition," list under methyl testosterone the following:

"Sublingual, 5 milligrams. Methyl testosterone usually available in tablets containing these amounts."

Therefore, your affiant alleges that the re-labeling of said products as represented by the Exhibits attached hereto, complies in all respects with the particulars in which the former labeling was alleged to be deficient in said criminal action, and that said re-labeling was done in good faith and under expert counsel and advice.

Your affiant further alleges that he is informed and believes and therefore alleges that the State law of California does not, nor does the Federal law,

require that methyl testosterone in linguet or tablet form be sold only by prescription of a physician. That notwithstanding said fact, the said Food and Drug Administration of the United States government will not approve any labeling of such product for sale without prescription regardless of the warnings that may be placed thereon and regardless of the fact that said labeling may, as the labeling involved herein does, repeatedly advise the user against the use of said product except under the supervision of a physician.

In answer to the allegations of Paragraph 6 of said Complaint, affiant alleges that shortly following the judgment in said criminal action, there remained certain window and store displays which had been there prior to the institution of said criminal action. That following said judgment, said window and store displays remained for a short period of time because of the press of business imposed upon affiant in attempting to organize said business in a manner that would comply with the evidence and the judgment in said criminal action, but that said window and [88] store displays have all been taken down and eliminated and none existed in the place of business of any of the defendants in this action at the time of the filing of the Complaint herein.

Affiant denies that he, or any of the defendants, since said judgment of conviction, have represented in any newspaper advertising that said drugs would be efficacious in alleviating a variety of disease conditions or those relating to sexual impotence in man and a change of life in women, and in this connection

affiant attaches hereto and marks as Exhibit "C" a true and correct copy of the only advertisements which have appeared in any newspapers since the date of said judgment.

With respect to the allegation contained in Paragraph 3 of said Complaint as amended, that the labeling of said product fails to bear adequate directions for use in all conditions for which said product is prescribed, recommended and suggested, affiant alleges that if such a position be tenable, then it would be impossible for any drugs to be sold to the laity or except upon prescription, and your affiant is informed and believes and therefore alleges in this connection that should this drug or any other drug be so labeled as to all possible conditions for which the same might be used, that said Federal Food and Drug Administration would consider such labeling as misleading and arbitrarily institute action therefor, criminal or civil.

/s/ MARTIN A. CLEMENS.

Subscribed and sworn to before me this 14th day of October, 1949.

[Seal] /s/ EUGENE M. ELSON,

Notary Public in and for

Said County and State. [89]

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and

FEMALE

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This discovery of the MALE SEX HORMONE is one of the achievements of modern medicine on which the public is comparatively uninformed. *Yet it is truly a tremendous accomplishment.*

PROF. RUZICKA, a Swiss chemist, succeeded in making TESTOSTERONE, "the most potent male hormone" by synthetic means; and for this he received THE ★ 1939 NOBEL PRIZE IN CHEMISTRY

"Science is unlocking the secrets of Male and Female sex hormones. Years of scientific effort and research have established that these hormones accomplish many things which up to a few years ago were thought to be impossible. These discoveries are far-reaching and assisting millions of men and women to lead happier lives, and are relieving and postponing the many conditions associated with middle age."

★ THE SEX HORMONES

All hormones play a major part in the sexual make-up of the hormonal system. The male hormone stimulates growth and development of the sex organs and of the male sex characteristics, such as distribution of hair, muscular development, depth of voice and the impression of a sense of well-being.

★ MALE HORMONE DEFICIENCY

The average man in his late forties begins to enter what is called the "climacteric" period in which time the body undergoes a radical change. Although most of these changes may start during middle age, they may also show up at almost any time during middle age. As a rule there may be flushes, sweats and chills. Lack of sexual potency, impaired memory, irritability, inability to concentrate on activities or a tendency to evade them, nervousness, depression, general weakness and poor physical strength are some of the major signs which are associated with this declining period.

★ IMPOTENCE

Lack of sexual desire and inability to perform the sexual act is one of the most common complaints of the male "climacteric." When due to a deficiency of the male sex hormone, these conditions usually respond promptly to male hormone therapy, which assist in restoring sexual desire and ability to fulfill it. In addition to re-establishing potency, the male sex hormone helps to relieve other conditions which frequently occur during this period.

★ RESULTS FROM MALE HORMONE

These social, sexual, physical and mental conditions may be overcome by the use of the male sex hormones, which often bring about startling changes. At first, it may be noticed there is a marked improvement in physical and mental work and a tonic action resulting in renewed vigor. A better attitude towards business and social life is frequently observed. Nervousness, exhaustion and melancholy gradually disappear and in the large majority of instances the improvement persists over a long period of time.

***Just One Tablet a Day Swallowed, and Eliminate
Unnecessary Injections***

NEW 25 mg TABLET

30 Tablets	\$10.00 Plus 3% Sales Tax
100 Tablets	29.95 Plus 3% Sales Tax
200 Tablets	57.50 Plus 3% Sales Tax

NO PRESCRIPTION REQUIRED

PRICES ON TESTOSTERONE FOR INJECTION BY REQUEST

MALE HORMONE

103

TESTOSTERONE

LINGUETS . . . under the tongue or behind the cheek

when Oral Male Hormone Therapy is Indicated

are effective in doses $\frac{1}{2}$ to $\frac{3}{4}$ the amount required when methyltestosterone is ingested. Greater economy, convenience and ease of administration mark Metandren Linguets as one of the great advances in androgenic therapy.

THE MOST ECONOMICAL ORAL ANDROGEN

The sublingual administration of methyltestosterone in the form of Linguets is based on direct venous drainage from the oral mucous membranes. The androgen is carried in the blood by the systemic venous system to the right heart, thence through the pulmonary circulation back to the left heart and thus is first distributed by the general circulation to all organs and tissues. By this route methyltestosterone by-passes the liver and escapes partial inactivation. Consequently complete dosage is delivered to the tissues more rapidly and without loss.

FOR LIMITED TIME ONLY
10% DISCOUNT
ON ALL ITEMS ON THIS PAGE

NEW TABLET
Adapted, Oct. 1948
Reg. U.S. Pat. Off.
MORE POWER
6 tablets equals one
20 mg. injection
DOUBLE STRENGTH

Box 50 Tablets Linguets.....	\$ 9.50 plus 3% sales tax
Box 100 Tablets Linguets.....	17.00 plus 3% sales tax
Box 200 Tablets Linguets.....	32.00 plus 3% sales tax
Box 500 Tablets Linguets.....	75.00 plus 3% sales tax

NO PRESCRIPTION REQUIRED

Many Excellent Reports for the Non Professional layman have already appeared in the following publications:

United States Phar.—April, 1947.

Readers Digest by Paul de Kruif, July, 1944—August, 1946.

Newsweek, March, 1943.

Time, May 28, 1945.

Newsweek, May 28, 1945.

Liberty, February 2, 1946.

True, February, 1945.

*Paul de Kruif's sensational book, "The Male Hormone," Harcourt-Brace.

*Send \$1.00 plus 15c for mailing.

**INFORMATION AND PRICES ON AMPULES OR VIALS
SENT BY REQUEST**

FEMALE HORMONE¹⁰⁴

A-ESTRADIOL

The estrogenic hormone promotes the development of sex characteristics in the female.

It maintains the normal condition of these characteristics in the normal adult woman.

a-Estradiol preparations confer a definite "sense of well-being."

a-Estradiol offers clinically important advantages.

a-Estradiol is the genuine hormone of the ovarian follicle, which is "probably the most potent of all known estrogens."

a-Estradiol has a smooth, dependable action which speedily controls the symptoms of ovarian deficiency and produces a gratifying sense of well-being. *a*-Estradiol is not likely to provoke side reactions or after-effects, such as headache, dizziness and gastrointestinal disturbances, which frequently complicate the action of artificial estrogens. Because of their high potency, oral *a*-estradiol tablets may be used in place of parenteral therapy in most cases. The elimination of frequent injections means not only more comfort and convenience for the patient—it also saves the physician both time and energy.

The especial therapeutic value of *a*-estradiol preparations, particularly as compared with estropipate (theobal) and estriol (theobal), is today widely appreciated, since the latter two appear to be secondary products of minor importance.

THE CHANGE OF LIFE

Although the climacteric which occurs between the fourth and fifth decades of life may pass with hardly any complications, in many women it may cause disorders which may interfere seriously with normal living. These disorders may be mild or severe, depending upon the individual. Headache, insomnia and dizziness are frequently complained of. In severe cases, there may be fear, crying spells sometimes accompanied by melancholy and emotional instability.

PRICES—A-ESTRADIOL TABLETS

30 Days Supply	\$10.00 Plus 3% Sales Tax
60 Days Supply	17.50 Plus 3% Sales Tax

BREAST DEVELOPMENT

DIRECT ACTION ON THE MAMMARY GLAND

Estrogens can be absorbed through the skin of the human female directly into the breast tissue and by this route can produce their characteristic stimulation of mammary growth and the result is "definite breast growth of considerable degree." Since underdeveloped breasts are often a considerable worry to women, cutaneous estrogen therapy of hypomastia presents a valuable addition to the physician's therapeutic resources.

25 Days Supply (50,000 International Units)	\$ 7.50	} Plus 3% Sales Tax
25 Days Supply (125,000 International Units)	14.00	
50 Days Supply (250,000 International Units)	25.00	

NO PRESCRIPTION REQUIRED

VITA HORMONES 100 Tablets

Each Tablet Contains 5 Mg Methyl Testosterone

SUGGESTED DOSAGE: One tablet upon arising before breakfast or one tablet shortly before retiring. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from three to six months, under supervision of a physician.

DIRECTIONS: For use by adult males deficient in male hormone when small dosages of male hormone are prescribed or recommended by a physician for palliative relief of such symptoms.

Distributed by **VITA PHARMACALS, INC.**
1109½ No. Western Ave. Hollywood 27, Calif.
Hollywood 9-1722

(Read Side Panels)

It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted, since testosterone will not aid or relieve symptoms not associated with male hormone deficiency. Children and young adults must not use testosterone without constant direct supervision of a physician.

CAUTION: The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention, probably by anyone with cardiovascular disease, defects of spermatogenesis, sterility, whether absolute or partial, or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed.

VITA HORMONES 100 Tablets

Each Tablet Contains 10 Mg Methyl Testosterone

SUGGESTED DOSAGE: One tablet upon arising before breakfast or one tablet shortly before retiring. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from three to six months, under supervision of a physician.

DIRECTIONS: For use by adult males deficient in male hormone when small dosages of male hormone are prescribed or recommended by a physician for palliative relief of such symptoms.

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VITA HORMONES 100 Tablets

Each Tablet Contains 25mg Methyl Testosterone

SUGGESTED DOSAGE: One tablet upon arising before breakfast or one tablet shortly before retiring. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from three to six months, under supervision of a physician.

DIRECTIONS: For use by adult males deficient in male hormone when small dosages of male hormone are prescribed or recommended by a physician for palliative relief of such symptoms.

Distributed by **VITA PHARMACALS, INC.**
1109½ No. Western Ave. Hollywood 27, Calif.
Hollywood 9-1722

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Exhibit C

H **NEW**
LOW COST MALE
HORMONES

TESTOSTERONE
NOW COMBINED WITH
VITAMIN B₁
mailed to you in plain
wrapper. Send check,
cash or money order.
CAUTION! Take only
as directed.

60
TABLETS
\$5.25
POSTPAID

VITA PHARMACAL CO. Dept. X7
1109 1/4 N. WESTERN AVE. HOLLYWOOD 27, CALIF.
FOR SALE IN CALIFORNIA ONLY

H **Sensational NEW**
FORMULA! MALE
HORMONES

TESTOSTERONE
NOW COMBINED WITH
VITAMIN B₁
at a new low price
Mailed to you in plain
wrapper. Send check,
cash or money order.
CAUTION! Take only
as directed.

60
TABLETS
\$5.25
POSTPAID

DOUBLE YOUR MONEY BACK Guarantee
If, after taking these tablets for at least 10 days, you
don't feel that you are deriving benefit from their use,
return box and the unused tablets and we will cheer-
fully give you **DOUBLE** your money back.

VITA PHARMACAL CO. Dept. X7
1109 1/4 N. WESTERN AVE. HOLLYWOOD 27, CALIF.

[Endorsed]: Filed October 24, 1949.

[Title of District Court and Cause No. 10266-PH.]

SUPPLEMENTAL AFFIDAVIT OF
MARTIN A. CLEMENS

State of California,
County of Los Angeles—ss.

Martin A. Clemens, being duly sworn, deposes and says:

That on or about October 14, 1949, he purchased from one of the Thrifty Drug Stores in Los Angeles three bottles each of Dr. Pierce's Favorite Prescription, Dr. Pierce's Golden Medical Discovery, Dr. Miles' Nervine and Lydia E. Pinkham's Vegetable Compound.

That the carton in which one of said bottles of Dr. Pierce's Favorite Prescription was contained is attached hereto, incorporated herein as though fully set forth and marked Exhibit "A." That enclosed within said carton was a pamphlet which your affiant attaches hereto, incorporates herein as though fully set [96] forth and marks Exhibit "B."

That the carton in which one of said bottles of Dr. Pierce's Golden Medical Discovery was contained is attached hereto, incorporated herein as though fully set forth and marked Exhibit "C." That there was no pamphlet or other literature enclosed within said carton.

That the carton within which one of said bottles of Lydia E. Pinkham's Vegetable Compound was contained is attached hereto, incorporated herein as though fully set forth and marked Exhibit "D."

That inside of said carton was a circular or pamphlet which is attached hereto, incorporated herein as though fully set forth and marked Exhibit "E."

That the carton in which one of said bottles of Dr. Miles' Nervine was contained is attached hereto, incorporated herein as though fully set forth and marked Exhibit "F." That within said carton of Dr. Miles' Nervine was a pamphlet or circular attached hereto, incorporated herein as though fully set forth and marked Exhibit "G."

/s/ MARTIN A. CLEMENS.

Subscribed and sworn to before me this 21 day of October, 1949.

[Seal] /s/ EUGENE M. ELSER,
Notary Public in and for
Said County and State. [97]

13 FLUID OZS.

EXHIBIT A

PRICE \$1.35

109

Dr. Pierce's

FAVORITE

Prescription

FOR WOMEN

Of Value in
Relieving

PERIODIC PAINS
and Associated
NERVOUSNESS
BACKACHE and
HEADACHE.

Due to Functional
Menstrual
Disturbances



REG. U. S. PAT. OFF.

ACTIVE INGREDIENTS

BLUE COHOSH ROOT (Caulophyllum Thalicteroides)
BLACK COHOSH ROOT (Cimicifuga Racemosa)
OREGON GRAPE ROOT (Berberis Aquifolium)
BLACK HAW (Viburnum Prunifolium)
VALERIAN ROOT (Valeriana Officinalis)
FALSE UNICORN ROOT (Helleborus Dioica)

NO ALCOHOL

DIRECTIONS: Take 2 teaspoonfuls with water
3 times a day, preferably before or after meals.

13 FLUID OZS.

PRICE \$1.35

Dr. Pierce's

FAVORITE

Prescription

FOR WOMEN

Of Value in
Relieving

PERIODIC PAINS
and Associated
NERVOUSNESS
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Due to Functional
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REG. U. S. PAT. OFF.

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BLACK HAW (Viburnum Prunifolium)
VALERIAN ROOT (Valeriana Officinalis)
FALSE UNICORN ROOT (Helleborus Dioica)

NO ALCOHOL

DIRECTIONS: Take 2 teaspoonfuls with water
3 times a day, preferably before or after meals.

Dr. Pierce's Favorite Prescription was formulated by an outstanding doctor, especially for women. When taken for a time, it is of value in relieving periodic pains and associated nervousness, backache and headache* due to functional menstrual disturbances. At the same time it aids the digestion of food. This helps build women up—helps make them stronger, with more resistance.

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*If these symptoms are due to any organic cause (chronic illness, etc.)

*If these symptoms are due to any organic cause (chronic illness, etc.)

For Women—Of Value in Relieving
PERIODIC PAINS and
Associated NERVOUSNESS,
BACKACHE and HEADACHE*

Due to Functional
Menstrual Disturbances

● Dr. Pierce's Favorite Prescription was formulated by an outstanding doctor, especially for women. When taken for a time, it is of value in relieving periodic pains and associated nervousness, backache and headache* due to functional menstrual disturbances. At the same time it aids the digestion of food. This helps build women up—helps make them stronger, with more resistance.

*If these symptoms are due to any organic cause (abnormalities discoverable by x-ray, physical examination, or laboratory tests), you should consult your doctor.

ACTIVE INGREDIENTS
of Dr. Pierce's
FAVORITE
PRESCRIPTION

Blue Cohosh Root
 (Caulophyllum Thalictrifolium)
 Black Cohosh Root (Cimicifuga Racemosa)
 Oregon Grape Root (Berberis Aquifolium)
 Black Haw (Viburnum Prunifolium)
 Valerian Root (Valeriana Officinalis)
 False Unicorn Root (Helonias Dioica)

Contains no alcohol or any harmful drug.

You can get Dr. Pierce's Favorite Prescription at your drug store.

PRICES

Handy Tablets for the Purse . . .

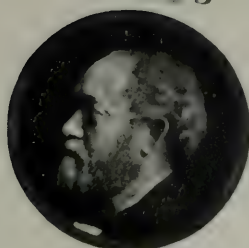
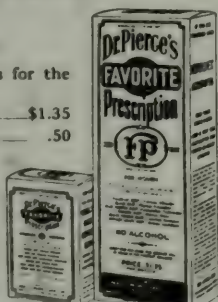
Economy Size . . . \$1.35

Medium Size50

LIQUID

Economy Size
 \$1.35

Medium Size
 \$1.00



HOW Dr. PIERCE
Developed

FAVORITE PRESCRIPTION

After completing his medical training, Dr. R. V. Pierce practiced medicine in western Pennsylvania, where he soon became widely known. Among the medicines he developed in his practice were two—Dr. Pierce's Favorite Prescription and Dr. Pierce's Golden Medical Discovery. Having found these prescriptions highly successful in his private practice, Dr. Pierce moved to Buffalo, N. Y., and founded a medical company to make his medicines available to everyone. Here he also founded a hospital that became famous throughout the country. Today, over 75 years after Dr. Pierce formulated his Favorite Prescription, it is continuing to grow in favor.

DIRECTIONS for using
Dr. Pierce's
FAVORITE
PRESCRIPTION

Take 2 teaspoonfuls or 2 tablets with water 3 times a day, preferably before or after meals.

Take the medicine regularly and faithfully, so that it has time to bring you the benefits you seek. If no improvement is noted within a reasonable time, consult your physician.

CAUTION: Cap the bottle when putting it away after each dose. If you are using the liquid medicine, shake the bottle thoroughly each time before using.

NOTE TO DIABETICS: 8 teaspoons of the liquid Favorite Prescription are equivalent to 4 teaspoonfuls of sugar. The tablets have only a little sugar in their coating.

FOR PEOPLE WHO ARE OCCASIONALLY CONSTIPATED

Recommended for
BOTH ADULTS AND CHILDREN

● If you occasionally have a dull headache suffer from loss of appetite—or feel sluggish and tired because of constipation—we believe you will find Dr. Pierce's Pleasant Purgative Pellets a most effective and pleasant laxative.

These pellets are very mild in action. Yet are highly effective in aiding nature to eliminate waste in the bowels. Very important, Dr. Pierce's Pleasant Purgative Pellets are so small (actually not much larger than the head of a pin) that they are easy to swallow. Even children as young as 8 years find them pleasant to take. You can get Dr. Pierce's Pleasant Purgative Pellets from your druggist.



Only 30c at any drug store.

**Dr. Pierce's
PLEASANT PELLETS**

100

We Recommend Dr. Pierce's
GOLDEN MEDICAL DISCOVERY

In Cases of

**GAS PAINS, HEART BURN
and Other Symptoms of
COMMON INDIGESTION**

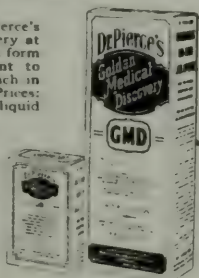
*When the Cause is Not Organic**

In such cases, Dr. Pierce's Golden Medical Discovery contains ingredients which promote more normal stomach and intestinal activity, so helping to digest food better and more thoroughly and over a period of time make gas pains and discomforts of indigestion less likely.

You can get Dr. Pierce's Golden Medical Discovery at your drug store in liquid form or in tablets convenient to carry to work or to lunch in your pocket or purse. Prices: Tablets \$1.35 and 50c; liquid \$1.35 and \$1.00.

If gas pains and indigestion persist, see your physician.

*These symptoms may be due to a number of other conditions. If you have any doubt regarding the cause of your symptoms, you should consult a doctor.



**People May Be
THIN, RUN-DOWN
and TIRE EASILY
Due to No Organic Cause*
But Due to Poor Appetite or
Poor Digestion**

If you are underweight, tire easily, and are run-down due to no organic cause—while your symptoms may be due to a number of other conditions—the answer may be simply this:

First, you may not have sufficient appetite to eat enough food; and, equally important, you may not be digesting your food properly.

Dr. Pierce's Golden Medical Discovery may help both ways. It contains ingredients which stimulate the appetite—helps make you really hungry—promotes more normal stomach and intestinal activity—and this, over a period of time, helps you digest and assimilate food in order to turn strength-building elements into energy, vitality, and added flesh.

*Organic cause means abnormalities discoverable only by x-ray, physical examination, or laboratory tests.

101

**A Diuretic and Analgesic
to Promote the Flow of Urine
and Relieve Muscular Pain!**

MANY PEOPLE SUFFER from the discomfort of scanty and over-frequent urination. They may have to get up several times at night, so that normal rest is disturbed. The scanty urine is concentrated; it may be acid and, hence, burn. Muscular pains may also be associated with this condition.

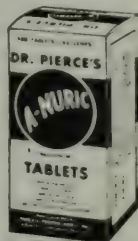
WHEN THESE SYMPTOMS are not due to any organic cause, Dr. Pierce's A-Nuric tablets are of value as a diuretic to promote the flow of urine and as an analgesic to relieve muscular pain.

THE URINE BECOMES less concentrated, alkaline instead of acid. Thus the painful acid irritation of the membrane should be gently relieved. The urge to over-frequent urination should be reduced. Hence sleep is less likely to be interrupted. And, because of their analgesic properties, Dr. Pierce's A-Nuric tablets should relieve muscular pains.

You can get Dr. Pierce's A-Nuric Tablets at your drug store.

Package of 100
tablets . . . 65c

**Dr. Pierce's
A-NURIC**



13 FLUID OZS.

PRICE \$1.50

We Recommend
Dr. Pierce's Golden
Medical Discovery

In cases of

GAS PAINS,
HEARTBURN
and other symptoms

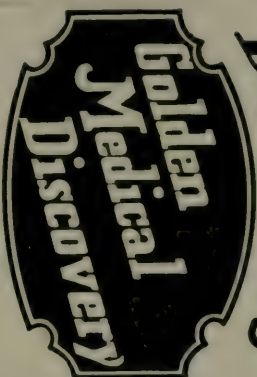
of COMMON
INDIGESTION

When the Cause is
not Organic*

In such cases Dr. Pierce's Golden Medical Discovery contains ingredients which promote more normal stomach and intestinal activity so helping to digest food better and more thoroughly and over a period of time make gas pains and discomforts of indigestion less likely.

If gas pains and indigestion persist, see your physician.

Dr. Pierce's



REG. U. S. PAT. OFF.

ACTIVE INGREDIENTS

OREGON GRAPE ROOT (Berberis Aquifolium)
CASCARA BARK (Rhamnus Purshiana)
QUEEN'S ROOT (Siliingia Syriatica)
WILD CHERRY BARK (Prunus Virginiana)
GENTIAN ROOT (Gentiana Lutea)
STONE ROOT (Collinsonia Canadensis)
BLOOD ROOT (Sanguinaria Canadensis)

NO ALCOHOL

DIRECTIONS, ADULTS. Take 1 teaspoonful with water 4 times a day, preferably one-half hour before meals and before retiring at night. After one week increase this dosage to 3 teaspoonfuls 4 times a day.

FOR CHILDREN. (6 to 15 years old) 1/2 to 1/4 adult doses. (15 to 18 years old) 1/4 to 3/4 adult dose.

People may be

THIN, RUN-DOWN
and TIRE EASILY

Due to no Organic
Cause* but due to
Poor Appetite or
Poor Digestion

If you are underweight, tire easily and are run down due to no organic cause—while your symptoms may be due to a number of other conditions—the answer may be simply this:

First you may not have sufficient appetite to eat enough food and equally important, you may not be digesting your food properly.

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13 FLUID OZS.

PRICE \$1.50

Dr. Pierce's



REG. U. S. PAT. OFF.

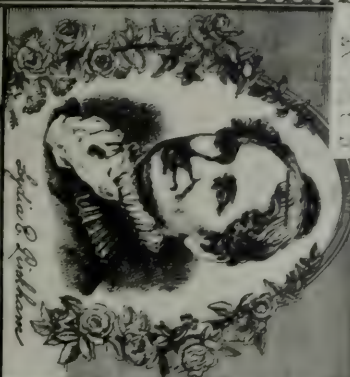
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FOR CHILDREN. (6 to 15 years old) 1/2 to 1/4 adult doses. (15 to 18 years old) 1/4 to 3/4 adult dose.



LYDIA E. PINKHAM'S VEGETABLE COMPOUND

WITH VITAMIN B₁
(THIAMIN)

15% Alcohol used solely as a solvent and preservative. This Compound contains Vitamin B₁ (Thiamin), Gentian, Buckthorn, True & False Unicorn, Life Root, Marsh, Dandelion, Chamomile, Peppermint Root.

When taken according to directions, this product supplies 333 U. S. P. Units (1 milligram) of Vitamin B₁ (Thiamin) per day, representing the normal minimum daily requirement.

Prepared by
LYDIA E. PINKHAM MEDICINE COMPANY
Lynn, Massachusetts, U. S. A.

One tablespoonful four times a day, before meals and at bedtime. Take Regularly throughout the month. Shake bottle well before using.

Directions:

When not due to organic disease. For particulars, see folder inside.

For relieving certain symptoms associated with and caused by the Menopause (Change of Life) and as a uterine sedative in Painful Menstruation



LYDIA E. PINKHAM'S VEGETABLE COMPOUND

WITH VITAMIN B₁
(THIAMIN)

15% Alcohol used solely as a solvent and preservative. This Compound contains Vitamin B₁ (Thiamin), Gentian, Buckthorn, True & False Unicorn, Life Root, Marsh, Dandelion, Chamomile, Peppermint Root.

When taken according to directions, this product supplies 333 U. S. P. Units (1 milligram) of Vitamin B₁ (Thiamin) per day, representing the normal minimum daily requirement.

Prepared by
LYDIA E. PINKHAM MEDICINE COMPANY
Lynn, Massachusetts, U. S. A.

For relieving certain symptoms associated with and caused by the Menopause (Change of Life) and as a uterine sedative in Painful Menstruation —

when not due to organic disease. For particulars, see folder inside.

Directions:

One tablespoonful four times a day, before meals and at bedtime. Take Regularly throughout the month. Shake bottle well before using.

Gift

A SEWING KIT that will fit in your handbag

A handy Sewing Kit will be sent you as a reward. All you need to do is to answer these few simple questions. Be sure to enclose carton top!

1. Where did you buy this product?

(name of store)

2. Date when you bought it

3. How much did you pay for it?

4. Is this the first bottle of the product you have used?

Name

Street Address

Town

County

State

We do not diagnose or prescribe or answer questions of a medical nature. Please do not ask us to do so.

Lydia E. Pinkham Medicine Company

LYNN, MASS.



VEGETABLE COMPOUND



For relieving certain symptoms associated with and caused by the Menopause (Change of Life) and as a uterine sedative in Painful Menstruation — when not due to organic disease.



Lydia E. Pinkham's Vegetable Compound is one of the most famous medicines ever made for girls and women to relieve certain distressing symptoms associated with and caused by Painful Menstruation and Change of Life, when not due to organic disease. For almost a century, thousands upon thousands of women have reported such benefit. Scientific clinical tests have strongly supported this efficacy of Pinkham's Compound. There are no opiates—no habit-forming or harmful ingredients in Pinkham's Compound. Instead, it contains nature's own roots and herbs plus Vitamin B₁. Lydia E. Pinkham's Compound is what is known as a uterine sedative, and tends to have a soothing, pain-relieving effect in dysmenorrhea. It is also an excellent stomachic tonic.

For a more particular statement of its benefits, turn the page.

Lydia E. Pinkham's Compound is recommended to relieve distress when not due to organic disease...

...IN PAINFUL MENSTRUATION:

In carefully conducted medical tests, most of the women studied received marked benefit, through relief of the distress from Painful Menstruation such as cramps, headache and backache. For over eighty years, the testimonials to the record and performance of Pinkham's Compound in relieving these functional menstrual disturbances have been impressive. So if you suffer distress from such a cause, why not give Pinkham's Compound a fair trial?

Pinkham's Compound often gives temporary relief from nervous, tired, irritable, 'dragged down' feelings, when due to functional dysmenorrhea. See if Pinkham's Compound is not the 'friend' you need to make such 'difficult days' more pleasant.

DIRECTIONS: One tablespoonful 4 times a day before meals and at bedtime. Take regularly throughout the month. *Note:* Pinkham's Compound helps build up *resistance* against such distress. Clinical tests showed greater relief obtained by those who took the Compound for more than two months. But naturally, relief must not be expected in all cases. If organic disease is present, a doctor should be consulted.

...IN CHANGE OF LIFE:

The Menopause (Change of Life) has generally been considered a great handicap to the happiness of middle-aged women (usually from 38 to 52 years of age). Many women suffer from 'hot flushes' and feel highstrung, restless and nervous at this time.

In scientific tests, Lydia E. Pinkham's Compound was shown to be of marked benefit to most of the women studied, in relieving distressing symptoms associated with and caused by the Menopause. In these medical tests 'hot flushes' were remarkably reduced, and the majority of women reported definite improvement in their sense of well-being. In most of the patients, the depression and moody feelings, often present during and caused by the Menopause, were greatly relieved.

Naturally, relief must not be expected in all cases or where trouble is due to organic disease. But if you are troubled by distressing symptoms commonly associated with Change of Life, why not try Pinkham's Compound?

DIRECTIONS: One tablespoonful 4 times a day—before meals and at bedtime. To be taken over a period of months. If expected relief is not obtained, a physician should be consulted.

110

Lydia E. Pinkham's TABLETS

Girls and women! The loss of blood during monthly periods may result in a deficiency in blood-iron, which is commonly known as simple anemia. For this reason you may feel pale, weak and "dragged out." In such cases, Lydia E. Pinkham's Tablets are an effective blood-iron tonic, to help build up and fortify red blood cells. They also have a stomachic tonic effect. Easy to take—easy to carry while traveling or away from home.

DIRECTIONS: Two tablets 4 times a day, before meals and at bedtime. Take regularly throughout the month.

Lydia E. Pinkham's SANATIVE WASH

(for vaginal diseases)

SANATIVE WASH is very effective in removing the discharge of LEUCORRHEA (commonly known as "the whites").

When used as directed SANATIVE WASH is 1. Antiseptic-germicidal 2. Cleansing 3. Deodorizing 4. Soothing. Safe to tissues. It relieves the discomforts of minor irritations, itching and burning. It promotes healing. SANATIVE WASH contains no harsh alkalies, phenols or mercury salts. It does not disturb the normal acidity which the vagina should have.

DIRECTIONS: Add two teaspoonfuls of SANATIVE WASH to each quart of warm water and mix well. Use as a vaginal douche in routine hygiene by means of a good fountain syringe.

Phenrin (to relieve simple headaches, muscular aches, pains accompanying colds and neuralgia)

Lydia E. Pinkham's Pills for Constipation

111

NET CONTENTS: 1½ FLUID OUNCES

NET CONTENTS: 1½ FLUID OUNCES

Exhibit F

MILES NERVINE

MILES NERVINE

MILES NERVINE

MILES NERVINE

ACTIVE INGREDIENTS

Each Teaspoonful (1/4 oz.) Contains
Sodium Bromide 4½ gr.
Potassium Bromide 4½ gr.
Ammonium Bromide ½ gr.
(Non-Alcoholic)



A Sedative

For the Following Functional Nervous Disturbances: Nervous Headache, Nervous Irritability and Excitability, Sleeplessness and Restlessness

ADULT DOSE:

1 or 2 teaspoonfuls in ½ glass of water. Take 1 teaspoonful at 1 hour if necessary. Do not exceed 3 teaspoonfuls in 24 hours.

CAUTION:

Use only as directed. Do not give to children. Over-dosage or habitual use, or use in the presence of kidney disease may be dangerous. If skin rash appears discontinue use. If nervous symptoms persist, see your physician.

Bromides have been used for many years in the treatment of functional nervous disturbances. Miles Nervine supplies Bromides in a well balanced palatable, easily administered form.

ACTIVE INGREDIENTS

Each Teaspoonful (1/4 oz.) Contains
Sodium Bromide 4½ gr.
Potassium Bromide 4½ gr.
Ammonium Bromide ½ gr.
(Non-Alcoholic)



A Sedative

For the Following Functional Nervous Disturbances: Nervous Headache, Nervous Irritability and Excitability, Sleeplessness and Restlessness

ADULT DOSE:

1 or 2 teaspoonfuls in ½ glass of water. Take 1 teaspoonful at 1 hour if necessary. Do not exceed 3 teaspoonfuls in 24 hours.

CAUTION:

Use only as directed. Do not give to children. Over-dosage or habitual use, or use in the presence of kidney disease may be dangerous. If skin rash appears discontinue use. If nervous symptoms persist, see your physician.

Bromides have been used for many years in the treatment of functional nervous disturbances. Miles Nervine supplies Bromides in a well balanced palatable, easily administered form.

MILES LABORATORIES, INC.

PRICE 25 CENTS

MILES LABORATORIES, INC.

PRICE 25 CENTS

MILES NERVINE (Liquid)

ACTIVE INGREDIENTS

Each Teaspoonful ($\frac{1}{8}$ oz.) Contains:

Sodium Bromide $4\frac{1}{2}$ gr.

Potassium Bromide $4\frac{1}{2}$ gr.

Ammonium Bromide $\frac{1}{2}$ gr.

(Non-Alcoholic)



INDICATIONS AND DOSAGE

Miles Nervine Liquid is effective as a sedative for the following *Functional Nervous Disturbances*:

LEEPLLESSNESS AND RESTLESSNESS

Insomnia or wakefulness at night can often be attributed to nervous or emotional excitability. One of the desirable effects of the active ingredients in Miles Nervine Liquid is to relieve insomnia by helping to relax nervous tension and so enabling one to fall asleep.

NERVOUS IRRITABILITY AND EXCITABILITY

For these, rest is the primary consideration. Modern strain and stress have placed a great load on our emotional machinery. Excitement prevents sensing of nervous fatigue of which irritability and excitability are symptoms. Miles Nervine Liquid is effective in helping to relieve the over-wrought nervous condition responsible for these symptoms.

NERVOUS HEADACHE

Worry, anxiety, and overwork frequently produce an upset or disturbed nervous system which may result in irksome nervous headaches. A sedative, such as Miles Nervine Liquid, will usually give soothing relief for headaches of this type. If a headache persists or recurs frequently, a physician should be consulted.

ADULT DOSAGE

One or two teaspoonfuls in $\frac{1}{2}$ glass of water. Take 1 teaspoonful in 1 hour if necessary but do not exceed 3 teaspoonfuls in 24 hours.

CAUTION

Use only as directed. Do not give to children. Over-dosage or habitual use, or use in the presence of kidney disease may be dangerous. If skin rash appears, discontinue use. If nervous symptoms persist, see a physician.

MILES LABORATORIES, INC., Elkhart, Indiana, U.S.A.

WHAT IS MILES NERVINE?

For more than sixty years Miles Laboratories has sold Miles Liquid Nervine. Its essential ingredients are the bromides of sodium, potassium and ammonium, long used as effective nerve sedatives. Bromides alone are salty and somewhat disagreeable in taste. Their presentation in a pleasant-tasting and convenient form together with the inherent good qualities of the bromides themselves has given Miles Nervine its wide public acceptance.

Miles Liquid Nervine is put up in two sizes; a large size containing 8 fluid ounces, the smaller size containing 1½ fluid ounces.



MILES NERVINE IN AN EFFERVESCENT FORM

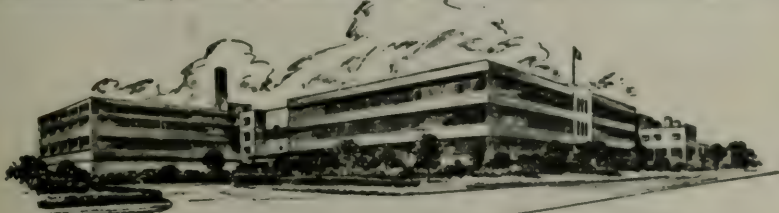
Miles Nervine is offered in a new convenient form, a compressed tablet consisting of the same time-tested active ingredients as Miles Liquid Nervine, combined with bicarbonate of sodium and citric acid, which dissolves in water with brisk effervescence to form a sparkling palatable solution.

For over sixty years the products of Miles Laboratories, Inc. have been sold subject to the consumer's entire satisfaction. Miles Nervine is no exception to this rule. If after trying your first package you are not satisfied, we will be glad to refund the purchase price.

EVERY SAFETY FACTOR IN PRODUCTION

The ingredients in Miles Nervine meet exacting standards of purity. Its manufacture is carefully controlled, with laboratory analysis by qualified chemists. Thus the consumer is given every safeguard and the assurance that Miles Nervine is as fine a preparation of its type as modern manufacturing can produce.

Miles Laboratories, founded in 1884, has developed consistently over the past sixty years and now occupies a building especially designed and equipped for research and manufacturing by modern methods. The plant is open to public inspection.



MILES LABORATORIES, INC., Elkhart, Indiana, U. S. A.

[Title of District Court and Cause No. 10266-PH.]

SUPPLEMENTAL AFFIDAVIT OF
MARTIN A. CLEMENS

Affiant alleges that with respect to the allegations contained in said Complaint for Injunction that 5-mg. per day of methyl testosterone have no therapeutic value in said criminal information in which he was named as a defendant, counts 12, 13 and 14, involved methyl testosterone linguets containing 5-mg. each of methyl testosterone, but that no charge, claim or contention was made in said information or during the trial of said criminal action that 5-mg. of said product had no therapeutic value.

That in addition thereto when the witness Hazen M. Parkinson called upon the Government's witness, Dr. Norris J. Heckle, he received from said witness a prescription for 500 [116] methyl testosterone linguets, each containing 5-mg. of methyl testosterone, with directions written by said Dr. Norris J. Heckle to take one per day.

/s/ MARTIN A. CLEMENS.

Subscribed and sworn to before me this 31 day of October, 1949.

[Seal] /s/ EUGENE M. ELSER,

Notary Public in and for
Said County and State.

[Endorsed]: Filed November 1, 1949. [117]

[Title of District Court and Cause No. 10266-PH.]

AFFIDAVIT OF LEWIS A. SCHINAZI

State of California,

County of Los Angeles—ss.

Before me, Robert S. Roe, an employee of the Federal Security Agency, Food and Drug Administration, designated by the Federal Security Administrator, under authority of the Act of January 31, 1925, c. 124, sec. 1, 43 Stat. 803, and Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940, to administer or take oaths, affirmatations, and affidavits, personally appeared Lewis A. Schinazi, in the county and State aforesaid, who, being first duly sworn, deposes and says:

(1) I am an inspector with the U. S. Food and Drug Administration, stationed at the Los Angeles District of the Administration, Los Angeles, California.

(2) On August 9, 1949, I purchased a carton of methyl testosterone without a prescription from the El-O-Pathic Pharmacy, 1109½ No. Western Avenue, Hollywood, California. At the time of this purchase, the representative of the El-O-Pathic Pharmacy who sold me the testosterone asked me for my name [118] and address, stating that he wished to keep me informed about new products in this field which might be of interest to me.

(3) On November 2, 1949, I received a commu-

nication through the U. S. Mail from Vita Pharmaceuticals, 11091½ No. Western Avenue, Hollywood 27, California. This communication consisted of three circulars which are attached to this affidavit as Exhibits A, B, and C. Exhibit A is entitled "Price List of Male Hormones"; Exhibit B is entitled "Retardar"; and Exhibit C is entitled "Special Introductory Offer."

/s/ LEWIS A. SCHINAZI.

Subscribed and sworn to before me at Los Angeles, California, November 3, 1949.

/s/ ROBERT S. ROE,

Employee of the Federal Security Agency, Designated Under Act of January 31, 1925, and Reorganization Plan IV Effective June 30, 1940.

Exhibit A

Vita Pharmacals
11091½ North Western Ave.
Los Angeles 27, Calif.

Price List of Male Hormones Methyl Testosterone 5 mg.

Regular Strength

<input type="checkbox"/>	50 Tablets.....	\$ 5.00 (Add 18c Tax)
<input type="checkbox"/>	100 Tablets.....	\$ 9.00 (Add 32c Tax)
<input type="checkbox"/>	500 Tablets.....	\$40.00 (Add \$1.39 Tax)
<input type="checkbox"/>	1000 Tablets.....	\$75.00 (Add \$2.63 Tax)

Methyl Testosterone 10 mg.

Double Strength

- ☐ 50 Tablets.....\$ 9.50 (Add 32c Tax)
☐ 100 Tablets.....\$17.00 (Add 58c Tax)
☐ 200 Tablets.....\$32.00 (Add \$1.10 Tax)
☐ 500 Tablets.....\$75.00 (Add \$2.63 Tax)

Name
 Address
 City..... Zone.... State.....

Please print name and address

☐ Cash ☐ C.O.D. ☐ Check or Money Order

I am an adult man, age.....

CAUTION: Take only as directed.

Exhibit B

Vita Pharmacals

1109½ No. Western Ave. Los Angeles 27, Calif.

“Retardar”

Helps Control Fast Ejaculation

Just a Few Drops Required

\$1.00 Trial Size

\$5.00 Size

Name
 Address
 City..... Zone State.....

Please print name and address

☐ Cash ☐ C.O.D. ☐ Check or Money Order

Exhibit C

⌘ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ ⌘

⌘ Special Introductory Offer ⌘

⌘ This Coupon is good for a 10 per cent Discount ⌘
⌘ on all of our Hormone Products. Act Now ⌘
⌘ and Save 10 Per Cent. Just deduct 10 per cent ⌘
⌘ from our price list. Your order will be ⌘
⌘ shipped immediately. ⌘

⌘ Send your order to:— ⌘

⌘ VITA PHARMACALS ⌘

⌘ 1109½ N. Western Ave. ⌘

⌘ Los Angeles 27, Calif. ⌘

⌘ This Offer Expires December 31, 1949 ⌘

⌘ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ ⌘

[Endorsed]: Filed November 3, 1949. [120]

[Title of District Court and Cause No. 10266-PH.]

AMENDMENT TO THE ANSWER

As a separate Affirmative Defense Defendants
allege:

I.

That for some time last past and now the Food
and Drug Administration of the Federal Security
Agency of the United States Government has in-
terpreted, applied and enforced and does now in-
terpret, apply and enforce Section 502(f)(1) of
the Federal Food, Drug and Cosmetic Act in an ar-
bitrary, capricious and unlawful manner, wherein

and whereby defendants herein are deprived of their property and liberty without due process of law in violation of Article V of the Amendments to the Constitution of the United States in the following particulars:

That officers, agents and representatives and employees of said Food and Drug Administration of the United States [123] Government have uniformly enforced, applied and interpreted Section 502(f) (1) of said Food, Drug and Cosmetic Act to mean that the term "adequate directions for use" as used in said Section enables and empowers them to decide and determine whether a particular drug and particularly methyl testosterone sold by defendants should or should not be sold over the counter to lay-persons regardless of the statements and contents of the labeling thereon; that should said officers of said Administration determine and decide that a particular drug and particularly methyl testosterone sold by the defendants should not be sold except on the prescription of a physician, no directions for use for sale of said product over the counter to lay-persons can be adequate and that the only manner in which, under such circumstances, the requirement that "adequate directions for use" be provided on the labeling is to provide thereon that said product should be sold only by or on the prescription of a physician. Notwithstanding the fact that there exists no act of Congress or rule or regulation by any Federal administrative body or tribunal prohibiting the sale of said product except on prescription.

By reason of said arbitrary, capricious and invalid interpretation of said statute applied and enforced by said administration and the officers, agents and employees thereof defendants are not nor are any of them enabled to know whether at any time any drug product sold by them is or is not in the opinion of said Food and Drug Administration a product which may be sold over the counter to lay-persons regardless of the statements and contents of the labeling thereon or should be sold only on the prescription of a physician.

By reason of said interpretation, application and enforcement of said statute defendants herein are subjected to possible prosecution under said Federal Food, Drug and Cosmetic Act at each time a shipment of a drug product is made in interstate [124] commerce, depending entirely upon the whim, opinion, decision or belief of said Food and Drug Administration rather than upon the provisions of said Section 502(f)(1) of the Federal Food, Drug and Cosmetic Act.

By reason of said interpretation, application, and enforcement of said statute as against these defendants they are deprived of their liberty and property without due process of law in violation of Article V of the Amendments to the Constitution of the United States.

II.

Defendants further allege that should said Section 502(f)(1) of the Federal Food, Drug and Cosmetic Act, properly interpreted, empower said Food and Drug Administration to apply and enforce said Sec-

tion as hereinbefore alleged, then said Section 502 (f)(1) of the Federal Food, Drug and Cosmetic Act constitutes an invalid delegation of legislative authority to an administrative body, to wit: The Food and Drug Administration of the Federal Security Agency of the United States.

HOWLETT and ELSON,

By /s/ EUGENE M. ELSON,
Attorneys for Defendants.

Duly verified.

[Endorsed]: Filed November 10, 1949. [125]

[Title of District Court and Cause No. 10266-HW.]

AFFIDAVIT OF WALTER F. McRAE

United States of America,
Southern District of California—ss.

Walter F. McRae, being first duly sworn, deposes and says that he is Acting Chief, Los Angeles District, Food and Drug Administration, Federal Security Agency, and that the following facts and documents are derived from his personal knowledge and from the official records of the Food and Drug Administration in his possession:

(1) A seizure action under the Federal Food, Drug, and Cosmetic Act is now pending in the United States District Court for the Western District of Pennsylvania, Civil No. 2719, against both

of the Dr. Pierce remedies referred to in the Supplemental Affidavit of Martin A. Clemens. The charge in that case is false and misleading labeling.

(2) The Lydia E. Pinkham preparation referred to in the Supplemental Affidavit of Martin A. Clemens is currently under investigation by the Food and Drug Administration.

(3) Attached hereto as Exhibit A is an advertisement of the Vita [129] Pharmacal Co. that appeared on page 12, Part II, of the Los Angeles Times on January 22, 1950.

(4) Attached hereto as Exhibit B is a copy of a letter dated January 16, 1950, which Dr. Wilton L. Halverson, Director of Public Health for the State of California, sent to the California State Board of Pharmacy. This letter sets forth a resolution adopted by the Board of Health recognizing the danger of selling hormones over the counter and by mail, and urges the Board of Pharmacy to consider the matter of restricting the sale of these drugs to prescription.

(5) The California State Board of Pharmacy has announced that beginning with February 7, 1950, public hearings will be held in Los Angeles and in San Francisco with respect to the question of whether male and female hormones should be placed on a dangerous drug list and thereby restricted to sale on prescription only.

/s/ WALTER F. McRAE,
Acting Chief, Los Angeles District, Food and Drug
Administration.

Subscribed and sworn to before me, this 27 day of January, 1950.

EDMUND L. SMITH,
Clerk, U. S. District Court, Southern District of
California.

By /s/ WM. A. WHITE,
Deputy. [130]

Exhibit A

[Newspaper advertisement.]

12 Part II—Sunday, Jan. 22, 1950

2*Los Angeles Times

Men Over 40*

The New Hormone Tablets
Testosterone Propionate.

Full potency. Officially listed as a United States Pharmacopeia preparation and formerly available only by injection, can now be taken by mouth in this new form! Mailed in plain wrapper. Send check, cash or money order today! (Caution—take only as directed.)

50 Tablets

Postpaid \$5.00, Double Strength, Postpaid \$9.00

Money Back Guarantee

If, after taking these tablets for at least 10 days,

*Men over 40 have a higher incidence of hormone deficiency than any other group.

you don't feel that you are deriving benefit from their use, return box and the unused tablets and we will cheerfully give you your money back.

Vita Pharmacal Co., Dept. T
1109½ N. Western Ave., Hollywood 27, Calif.

Exhibit B
(Copy)

January 16, 1950.

California State Board of Pharmacy
Room 313
507 Polk Street
San Francisco, 2, California

Gentlemen:

Attention: Mr. Linnet M. Walsh, Secretary

At the meeting of the State Board of Public Health on December 9, 1949, in Los Angeles there was discussion pertaining to the sale of hormones in the State of California.

After careful review of all the circumstances of advertising, distributing and labeling methods, and the dangers of improper use of these drugs, the Board took the following action which is quoted from the minutes of its meeting of December 9.

“Dr. Belt moved, Dr. Henderson seconded and the motion carried that recognizing the danger of selling hormones over the counter and by mail, the Board urges that the matter of restricting the sale of these drugs by prescription be considered by the State Board of Pharmacy.”

The Department of Public Health, after careful study of the problems involved in the sale of these hormones considers that over-the-counter sale of the following preparations, including combinations, derivatives, compounds, and mixtures thereof is against public policy since these articles are dangerous to health except when used under medical supervision:

Testosterone

Methyl Testosterone

Testosterone Cyclopentenyl Propionate

Androsterone

Dehydro-Androsterone [132]

Estrone

Estradiol

Estriol

Equilin

Equilenin

Hippulin

Hexestrol

Benzestrol

Androstene Dione

Androstene Diol

Appropriate regulations to limit the sale of these products to prescription, with the exception of ointments containing estrogenic ingredients in a quantity providing less than 10,000 International Units of Estrone or equivalent potency per ounce, intended solely for cosmetic use, should be promulgated under Division 22, California Health and Safety Code, Dangerous Drugs Act or other appro-

priate provisions of the Health and Safety Code.

It is hereby recommended that the California State Board of Pharmacy declare the above-mentioned preparations, combinations, derivatives, compounds, and mixtures to be dangerous drugs within the meaning of Section 29001, Division 22 of the California Health and Safety Code.

The product, Stilbestrol (Diethyl-Stilbestrol) is already declared a dangerous drug under Section 29001-E of the California Health and Safety Code and no further action is needed with respect to these.

Very sincerely yours,

/s/ WILTON L. HALVERSON,
WILTON L. HALVERSON, M.D.
Director of Public Health.

[Endorsed]: Filed January 27, 1950. [133]

[Title of District Court and Cause No. 10266-HW.]

AFFIDAVIT OF ALBERT H. WELLS

State of California,
County of Los Angeles—ss.

Before me, Robert S. Roe, an employee of the Federal Security Agency, Food and Drug Administration, designated by the Federal Security Administrator, under authority of the Act of January 31, 1925, c 124, sec. 1, 43 Stat. 803, and Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940, to administer or take oaths, affirmations, and affidavits, personally appeared Albert H. Wells, in

the county and State aforesaid, who, being first duly sworn, deposes and says:

(1) I am 64 years of age, and am a chemist with the U. S. Food and Drug Administration, stationed at the Los Angeles District of the Administration, Los Angeles, California.

(2) On November 22, 1949, I went to the store of Vita Pharmacals, Inc., at 11091½ North Western Avenue, Los Angeles, California, accompanied by my wife.

(3) When I entered the store with my wife, one of the men from [134] the rear of the store came up behind the sales counter to wait on me. I asked him to tell me about the medicine displayed in the window as "Male Hormone Combined with Vitamin B-1."

(4) The salesman took a small carton from a shelf, broke it open, pulled out a cellophane ribbon containing units of 2 compressed tablets at regular intervals. He handed the carton and contents to me. The label appeared to be the same as Exhibit D of the Answer filed by the defendants in the case of U. S. v. El-O-Pathic Pharmacy, Inc., et al., Civil No. 10266-HW, pending in the U. S. District Court for the Southern District of California.

(5) The salesman asked me whether I had prostate trouble or cancer. I told him I did not. I told him I was taking some vitamins and thought I would inquire about this hormone preparation containing vitamins.

(6) The salesman asked my age. I told him I am 64. He handed me a bottle of 5-milligram methyl

testosterone tablets labeled in part "Ciba," saying I should take that preparation instead. After looking at the label on this bottle, I asked whether I had to see a doctor or get a prescription. He said that was not necessary. He said I could have the hormone and vitamin combination product if I wanted it, but he strongly recommended my buying the Ciba bottle. He said I would be getting more for my money. His suggestion was that the tablets be taken by placing one under the tongue three times a day. If this were done, he said, I would feel a change within a few days. I left the store saying that possibly I should consult my physician as to which product to take.

(5) On November 23, 1949, I again went to the store of Vita Pharmacals, Inc., at 11091½ North Western Avenue, Los Angeles, California.

(6) When I entered the store, another man from the rear of the store came up behind the sales counter to wait on me. I told him I had been in the day before and wanted to speak to the heavy-set gentleman who had waited on me at that time. He said that man was not in but that he would serve me instead.

(7) I explained that the other salesman had recommended the use of methyl testosterone and that I would like to purchase a bottle. The salesman [135] then showed me a large bottle of 500 tablets labeled in part "Ciba," costing \$40.

(8) I asked if they had something less expensive. He showed me a small cardboard carton priced at \$17. I told him I preferred to have the tablets

in a bottle. He then removed a bottle from the shelf, stating he would have to change the label before he could sell it.

(9) I asked him why he had to change the label, and he stated that he would have to put on a new label; otherwise it could not be sold. I asked him what was wrong with it. He said, "Nothing." He also stated that he had heard from those who had purchased it at their store that this preparation of 5 or 10 milligrams of Methyl-Testosterone not only benefited them for what it was designed, but also helped their rheumatism and other troubles. He emphasized to me again that this property of the drug had only been told him by other persons.

(10) I asked him which was better to be taken—the 5 milligrams or the 10 milligrams Methyl-Testosterone—and he suggested using the 10-milligram tablet. I asked him why and he stated that they were double strength and would give me quicker action. In fact, he stated that I could take more than 3 a day of the 10-milligram dosage if I preferred and without harm to myself. I asked him how I would know when they would harm me, and he said they would not harm me but that I didn't need to take them all the time but only when I needed them.

(11) He said that he would reduce the price if I would take 100 tablets of the double-strength Methyl-Testosterone. The price reduction was from \$17 to \$15 plus 58c tax. He volunteered the following information, by saying, "You know you cannot get these at any other place without a prescription."

(12) The salesman then departed for the rear of the store stating he would relabel the bottle. A few minutes later he returned and handed me an unsealed wrapped package. On my inquiry, he assured me that this was the 10-milligram product. I paid him \$15.58 and left the store with the package.

(13) The contents of this package consisted of the following (1) a bottle with a yellow label, this label being identical with the yellow label in Exhibit A of the Answer filed by the defendants in the case of [136] U. S. v. El-O-Pathic Pharmacy, Inc., et al., Civil No. 10266-HW, pending in the U. S. District Court for the Southern District of California; (2) a circular entitled "Price List of Male Hormones," this circular being identical with Exhibit A of the affidavit of Lewis A. Schinazi in the above-identified case; and (3) a business reply envelope (no postage necessary) addressed to Vita Pharmacals, Inc., 1109½ No. Western Ave., Los Angeles 27, California.

/s/ ALBERT H. WELLS.

Subscribed and sworn to before me at Los Angeles, California, November 23, 1949.

/s/ ROBERT S. ROE,

Employee of the Federal Security Agency, Designated Under Act of January 31, 1925, and Reorganization Plan IV Effective June 30, 1940.

[Endorsed]: Filed January 27, 1950. [137]

[Title of District Court and Cause No. 10266-HW]

SUPPLEMENTAL AFFIDAVIT OF
ROBERT S. ROE

United States of America,
Southern District of California—ss.

Robert S. Roe, being first duly sworn, deposes and says that he is Chief, Los Angeles District, Food and Drug Administration, Federal Security Agency, and that the following facts and documents are derived from his personal knowledge and from the official records of the Food and Drug Administration in his possession:

(1) During the months of October and November, 1949, I conducted two investigations to ascertain whether the labeling of the male hormone products distributed by Vita Pharmacal Co., et al., defendants in the above-identified proceeding, in fact cause purchasers to consult physicians before taking the drugs.

(2) Three inspectors, who work in the Los Angeles Food and Drug office under my supervision, personally interviewed a total of 19 persons who were known to have purchased the product called "Male Hormone (Methyl Testosterone) Combined with Vitamin B-1" from Vita Pharmacal Co., 1109½ North Western Avenue, [138] Los Angeles, California, during the month of September, 1949. None of these 19 purchasers was in any way connected with the Food and Drug Administration.

(3) The inspectors obtained affidavits from 5 of the 19 persons interviewed. These affidavits are

attached to my affidavit and are identified as Exhibits A, B, C, D, and E, respectively.

(4) Said inspectors, in the regular performance of their duties, have submitted written reports to me describing each of these 19 interviews. The reports are a part of the official records of the Food and Drug Administration in my custody.

(5) Of the 19 persons interviewed, 2 were in their late forties, 9 were in their fifties, 4 were in their sixties, and 4 were in their seventies.

(6) These reports show that of the 19 persons interviewed, only one person was deterred from taking any of the testosterone as a result of reading the label. After reading the label, that one person decided not to use the product until he consulted a physician to find out if it was safe and might help him. At the time of the interview, he had not yet consulted a physician.

(7) Another of the 19 persons interviewed had ordered the drug, but about the time that he received it he had read a magazine or newspaper article warning of the dangers involved in the unsupervised use of hormones. For this reason, he decided not to take any.

(8) Still another of the 19 persons interviewed had been buying male hormones from El-O-Pathic Pharmacy (later Vita Pharmacals) since June or July of 1949. Prior thereto he had been taking what he thought were male hormone tablets prescribed for him by a physician some time ago. This person felt that the hormone tablets he obtained from El-O-Pathic Pharmacy were not of as much

value as those he had obtained on prescription. He also thought they caused tension around his heart and nervousness. For these reasons, he decided to discontinue taking these tablets.

(9) The remaining 16 persons of the 19 interviewed commenced taking the male hormones on receiving them from Vita Pharmacals without first consulting a physician.¹ Of these 16, 1 stated he had consulted a physician [139] about 3 months before ordering the hormones and had been advised that the physician would not recommend male hormones for a man of his age. Nevertheless, that person ordered the hormones by mail and took them without further consultation with his physician.

Five of the 16 who took the hormones without consulting a physician said that they thought they were safe in doing so because at some time in the past a physician had given them "hormone" shots or had prescribed hormones for them. Of these 5, one had received hormones from his physician a year before; three persons had received hormones from their physicians 2 years before; and one person had received hormones from his physician 4 years before.

Another of these 16 persons had been purchasing male hormones from El-O-Pathic Pharmacy and Vita Pharmacals, Inc., for 2 years. He had not consulted a physician before he began taking the hor-

¹One of these 16 persons was not at home when the inspector called, but the wife of that person furnished the inspector with the information sought.

mones and he continued taking them without consulting a physician. In September of 1949, in the course of being given a physical examination by a physician, he mentioned that he was taking hormones and he states he was advised he could continue taking them.

Another of these 16 persons began taking the hormones but shortly thereafter was advised by a friend that hormones may cause cancer and should not be used without medical advice. Whereupon, that person discontinued taking the hormones.

/s/ ROBERT S. ROE,
Chief, Los Angeles District, Food and Drug Administration.

Subscribed and sworn to before me, this 1st day of December, 1949.

EDMUND L. SMITH,
Clerk, U. S. District Court, Southern District of California.

By /s/ WM. A. WHITE,
Deputy. [140]

Exhibit A

AFFIDAVIT

FD463a

State of California
County of Los Angeles

Before me, Ola H. Bain, an employee of the Federal Security Agency, Food and Drug Admin-

istration, designated by the Federal Security Administrator, under authority of the Act of January 31, 1925, c. 124, sec. 1, 43 Stat. 803, and Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940, to administer or take oaths, affirmations, and affidavits, personally appeared Walter E. Wright in the county and State aforesaid, who, being first duly sworn, deposes and says:

I am 71 years of age.

I reside at 200 S. Putney Ave., San Gabriel, Calif.

About 3 months ago I inquired of Dr. Edison our family physician who maintains an office on Rosemead Avenue near my home, regarding the advisability of taking male sex hormones. The doctor said that he would not recommend them for a man of my age.

Soon thereafter I noticed a hormone advertisement by the El-O-Pathic Pharmacy in the Los Angeles Times and I decided to try the product. I ordered and received the 5 mg. Testosterone by mail, and subsequently re-ordered once or twice.

About 2 months ago I received a notice from the El-O-Pathic Pharmacy advising that the Vita-Pharmacals Company was taking over distribution of their products. [141]

Soon thereafter I ordered and received from this firm (Vita-Pharmacals Co.) a 30 tablet package of the combined hormone and vitamin product.

Taking the hormone preparations has resulted in

considerable improvement in my physical, mental and sex powers.

I have never been advised by a physician that my own hormone output was deficient or that I should take the products for any reason whatsoever, and I have not consulted a physician since receiving the El-O-Pathic or Vita-Pharmacals hormone preparations.

/s/ WALTER E. WRIGHT.

Subscribed and sworn to before me at San Gabriel, Calif., this 22nd day of November, 1949.

/s/ OLA H. BAIN,

Employee of the Federal Security Agency, Designated Under Act of January 31, 1925, and Reorganization Plan IV, Effective June 30, [142] 1940.

Exhibit B

Affidavit

State of California
County of Los Angeles

Before me, Robert W. Jennings, an employee of the Federal Security Agency, Food and Drug Administration, designated by the Federal Security Administrator, under authority of the Act of January 31, 1925, c. 124, sec. 1, 43 Stat. 803, and Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940, to administer or take oaths, affirmations, and affidavits, personally appeared Mr. K. V. Johnson in the county and State aforesaid, who, being first duly sworn, deposes and says:

I am a man of 72 years of age now residing at 10356 San Carlos, South Gate, California. The following information is given of my own free will and is true to the best of my knowledge.

Immediately prior to Sept. 19, 1949, I ordered tablets consisting of Male Hormone and Vitamin B-1 from the Vita Pharmacals Inc. of 1109½ N. Western Ave., Hollywood, California. This order was the result of noting hormone advertisements in the local newspaper.

On or about September 19, 1949, I received a shipment in the mail from the above-named company and this consisted of literature about hormones and vitamin B-1 along with a package of the tablets. This package was marked with the name of "Maywood Pharmacal Company" but in addition carried a sticker-label designating re-orders were to be sent to the "Vita Pharmacals," "distributors." There were 60 tablets in a cellophane roll within the package (or box), 30 of these being brown in appearance and 30 yellow in color. One tablet of each color was included in each section of the cellophane roll of merchandise. [143]

My purpose in purchasing the Hormone-Vitamin B-1 tablets was an attempt in aiding, is possible, a feeling of being tired and lack of energy. My thought was that these tablets might be of such value to me.

I took 50 of the 60 tablets sent to me, these being taken according to the direction on the box—that is, one tablet of each color per day—and feel that the product did me no harm and yet was of no value. I do have a catarrh condition and when taking these

tablets seemed to have a nose and throat drainage. I do not know if the drainage was caused by the tablets, but when I ceased taking the product, the condition ceased to exist.

I have never consulted a physician relative to the taking of male hormones.

/s/ K. V. JOHNSON.

Subscribed and sworn to before me at 10356 San Carlos, South Gate, California, this 27th day of October, 1949.

/s/ ROBERT W. JENNINGS,

Employee of the Federal Security Agency, Designated Under Act of January 31, 1925, and Reorganization Plan IV, Effective June 30, [144] 1940.

Exhibit C
Affidavit

FD463a

F.S.A. F.D.A.

State of California

County of Los Angeles

Before me, Robert W. Jennings, an employee of the Federal Security Agency, Food and Drug Administration, designated by the Federal Security Administrator, under authority of the Act of January 31, 1925, c. 124, sec. 1, 43 Stat. 803, and Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940, to administer or take oaths, affirmations, and affidavits, personally appeared Mr. E. C. Fessler in the county and State aforesaid, who, being first duly sworn, deposes and says:

I am a man of 52 years of age now residing at 4831 East 61st St., Maywood, California. The following information is given of my own free will and true to the best of my knowledge.

I have not seen a physician in over 10 years and until recently have never taken Hormone preparations. Approximately one month ago, after noting Hormone-Vitamine B-1 tablet ads in the Los Angeles Examiner paper, I ordered a supply of 60 tablets from the Vita Pharmacal Inc., N. Western Ave., Hollywood. These were received and found to be tablets in a cellophane stripping. Half of the tablets were brown in color and half were yellow. I took these as directed on the box and later ordered a second shipment of tablets. These were received approximately 1 week ago and consisted of white tablets of Male Hormone only, in the amount of 100/5 mg tablets. I have thrown away the containers for both shipments of tablets but remember their directions on the label.

I purchased this merchandise in an attempt to alleviate a tired, all-in feeling which I have had at times for the last eight or nine years. I have only about 3 days dosage remaining from my first shipment of merchandise and on completion of this will take the tablets sent me on the second order. To date I have had no results and can see no harm from those tablets taken. I intend to take all tablets in order to give the merchandise a fair trial. If I have

not improved by that time, I intend to cease use of them.

/s/ E. C. FESSLER.

Subscribed and sworn to before me at 4831 E. 61st St., Maywood, California, this 27th day of October, 1949.

/s/ ROBERT W. JENNINGS,

Employee of the Federal Security Agency, Designated Under Act of January 31, 1925, and Reorganization Plan IV, Effective June 30, [145] 1940.

Exhibit D

Affidavit

FD463a

State of California,
County of Los Angeles.

Before me, Robert C. Brandenburg, an employee of the Federal Security Agency, Food and Drug Administration, designated by the Federal Security Administrator, under authority of the Act of January 31, 1925, c. 124, sec. 1, 43 Stat. 803, and Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940, to administer or take oaths, affirmations, and affidavits, personally appeared C. W. Mingura in the county and State aforesaid, who, being first duly sworn, deposes and says:

I am a man of 47 years of age. On or about 9/12/49, in response to an ad I read in the Los Angeles Daily News, I ordered some Male Hormones from the Vita Pharmacal Company, Los Angeles.

The hormones were sent to me in a day or so via U.S. Mail. I read the label on the product but didn't follow the directions—I took the material at only about half the suggested frequency. I ordered the product because I thought that the combination of Vitamin B-1 and Hormones might be good for me and give me more energy. I feel that I obtained neither good nor bad results from the use of the product, but then again I didn't expect too much in the first place. I was not told by a doctor to take these hormones, and no doctor has ever told me that I need hormones.

/s/ C. W. MINGURA,

409 E. 21st St., Los Angeles,
Calif.

Subscribed and sworn to before me at Los Angeles, California, this 22nd day of November, 1949.

/s/ ROBERT C. BRANDENBURG,

Employee of the Federal Security Agency, Designated Under Act of January 31, 1925, and Reorganization Plan IV, Effective June 30, [146] 1940.

Exhibit E
Affidavit

FD463a

State of California

County of Los Angeles

Before me, Robert C. Brandenburg, an employee of the Federal Security Agency, Food and Drug Administration, designated by the Federal Security Administrator, under authority of the Act of Janu-

ary 31, 1925, c. 124, sec. 1, 43 Stat. 803, and Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940, to administer or take oaths, affirmations, and affidavits, personally appeared W. L. Durrive in the county and State aforesaid, who, being first duly sworn, deposes and says:

I am a man of 68 years of age. On or about 9/8/49, in response to an ad I read in the Los Angeles Examiner, I ordered some Male Hormones from the Vita Pharmacal Company, Los Angeles. The hormones were sent to me in a day or so via U.S. Mail. I didn't bother reading the label of the product other than the suggested dosage. I feel that the hormones built me up and made me feel better. I was not told by a doctor to take these hormones, and no doctor has ever told me that I need hormones.

/s/ W. L. DURRIVE,
2415 West Jefferson Ave.,
Los Angeles, Calif.

Subscribed and sworn to before me at Los Angeles, California, this 22nd day of November, 1949.

/s/ ROBERT C. BRANDENBURG,
Employee of the Federal Security Agency, Designated Under Act of January 31, 1925, and Reorganization Plan IV, Effective June 30, 1940.

[Endorsed]: Filed January 27, 1950. [147]

In the United States District Court for the Southern
District of California, Central Division

Civil No. 10266-HW

UNITED STATES OF AMERICA,

Plaintiff,

vs.

EL-O-PATHIC PHARMACY, a Corporation;
MARTIN A. CLEMENS, an Individual, and
VITA PHARMACALS, INC., a Corporation,
Defendants.

FINDINGS OF FACT AND CONCLUSIONS OF
LAW ON PRAYER FOR PRELIMINARY
INJUNCTION

This Court, having considered the pleadings, affidavits, briefs, and oral arguments relating to the plaintiff's prayer for a Preliminary Injunction in this cause, and having denied said prayer on January 11, 1950, now makes the following Findings of Fact and Conclusions of Law, but expressly refrains from making any determination with respect to the ultimate issues of fact and law:

Findings of Fact

(1) If the defendants are violating the Federal Food, Drug, and Cosmetic Act, the public interest can be substantially protected by an early trial on the plaintiff's prayer for a Permanent Injunction.

(2) This cause was set for trial in this Court on January 24, 1950, on the plaintiff's prayer for a Permanent Injunction, and on stipulation of the parties the trial date was continued until January 31, 1950. [148]

Conclusions of Law

(1) Where the United States seeks a Preliminary Injunction to prevent alleged violations of the Federal Food, Drug, and Cosmetic Act, and it appears that an early trial can be had on the prayer for a Permanent Injunction which will substantially protect the public interest involved, a Preliminary Injunction should not issue.

(2) The plaintiff's prayer for a Preliminary Injunction is denied.

Dated: Jan. 30th, 1950.

/s/ HARRY C. WESTOVER,

United States District Judge.

Received copy of the within Findings of Fact and Conclusions of Law this 27th day of January, 1950.

/s/ EUGENE M. ELSON,

Attorney for Defendants.

Judgment entered Jan. 30, 1950.

[Endorsed]: Filed January 30, 1950. [149]

[Title of District Court and Cause No. 10266-HW.]

STIPULATION AS TO RECORD

In order that this case may be disposed of as quickly as possible,

It Is Stipulated by the parties hereto, through their respective counsel, that the complete record of this case shall consist of the following documents, all of which are filed in Civil No. 10266-HW, unless otherwise stated:

(1) The Complaint for Injunction and the Amendment to Complaint for Injunction filed by the plaintiff;

(2) The supporting affidavits filed by the plaintiff together with their exhibits—namely, the affidavits of Mr. Robert S. Roe, Dr. Clinton Hobart Thienes, Dr. Elmer Belt, Dr. Ian Macdonald, and Mr. Lewis A. Schinazi;

(3) Judge Jacob Weinberger's Order Granting Temporary Restraining Order, dated September 2, 1949;

(4) Judge Jacob Weinberger's Order to Show Cause, dated September 2, 1949;

(5) Stipulation, Consent, and Order, signed by Judge Peirson M. Hall, [150] dated September 6, 1949, continuing hearing on Order to Show Cause;

(6) Stipulation, Consent, and Order, signed by

Judge Peirson M. Hall, dated September 26, 1949, continuing hearing on Order to Show Cause;

(7) Answer and Amendment to the Answer filed by the defendants;

(8) Stipulation Permitting Filing of Amendment to Answer, dated November 10, 1949;

(9) Affidavit of Martin A. Clemens and two supplemental Affidavits of Martin A. Clemens;

(10) Affidavit of Eugene M. Elson;

(11) Findings of Fact and Conclusions of Law of Judge Westover denying plaintiff's prayer for a Preliminary Injunction;

(12) Supplemental Affidavit of Robert S. Roe, subject to any objections as to relevancy and materiality;

(13) Affidavit of Albert H. Wells, subject to any objections as to relevancy and materiality;

(14) Affidavit of Walter F. McRae, subject to any objections as to relevancy and materiality;

(15) The Information filed by the Government in United States v. El-O-Pathic Pharmacy and Martin A. Clemens, No. 20596-Criminal (S.D. Calif.);

(16) The complete transcript of proceedings in the case described in paragraph (15), including exhibits, shall be considered part of the record of this case subject to any objections as to its relevancy and materiality;

(17) Stipulation and Order filed January 17, 1950, continuing the trial in this cause for one week.

ERNEST A. TOLIN,
United States Attorney.

CLYDE C. DOWNING,
Assistant U. S. Attorney,
Chief of Civil Division.

/s/ TOBIAS G. KLINGER,
Assistant U. S. Attorney,
Attorneys for Plaintiff.

HOWLETT and ELSON,
By /s/ EUGENE M. ELSON,
Attorney for Defendants.

[Endorsed]: Filed January 31, 1950. [151]

At a stated term, to wit: The September Term, A.D. 1949, of the District Court of the United States of America, within and for the Central Division of the Southern District of California, held at the Court Room thereof, in the City of Los Angeles on Tuesday, the 31st day of January in the year of our Lord one thousand nine hundred and fifty.

Present: The Honorable Charles C. Cavanah,
District Judge.

[Title of Cause No. 10266-HW-Civil]
and

[Title of Cause No. 10391-HW-Civil]

ORDER CAUSES CONSOLIDATED

These consolidated causes coming on for trial:
Geo. E. Danielson, Ass't. U. S. Att'y., appearing as

counsel for Gov't.; E. M. Elson, Esq., appearing as counsel for defendants; Attorney Danielson answers ready; and Attorney Elson answers ready and states that the causes are not consolidated for trial.

The Court orders the causes consolidated for trial and states it will bear in mind the separate contentions in each cause.

Attorney Danielson make opening statement and reads stipulation as to the record in each case, and said stipulation is filed herein.

Counsel having rested upon the record stipulated to in each case, Attorney Danielson argues in behalf of plaintiff. At 10:55 a.m. Court recesses.

At 11:10 a.m. court reconvenes herein and all being present as before, including counsel for both sides; Attorney Danielson argues further. Attorney Elson argues for defendants. At 11:55 a.m. court recesses. [259]

At 2 p.m. court reconvenes herein and all being present as before, including counsel for both sides; Attorney Elson argues further for plaintiff in closing. Attorney Elson argues further. Counsel stipulate to furnish transcript and the Court orders cause stand submitted.

Supplemental authorities of plaintiff are filed. [260]

At a stated term, to wit: The September Term, A. D. 1949, of the District Court of the United States of America, within and for the Central Division of the Southern District of California, held at the Court Room thereof, in the City of Los Angeles, on Friday the 3rd day of February in the year of our Lord one thousand nine hundred and fifty.

Present: The Honorable Charles E. Cavanah,
District Judge.

[Title of Cause No. 10266-HW-Civil]

and

[Title of Cause No. 10391-HW-Civil]

ORDER CAUSES REFERRED FOR RE-ASSIGNMENT

Geo. E. Danielson, Ass't. U. S. Att'y., appearing as counsel for Gov't., and Hallam Mathews, Esq., appearing in behalf of Eugene M. Elson, Esq., attorney for defendants, now come before the Court in Chambers, whereupon the Court states that after the causes were finally submitted, the Court finds itself disqualified from proceeding further in these consolidated causes and orders same referred to Judge McCormick for re-assignment. [261]

[Title of District Court and Cause No. 10,266-HW.]

FINDINGS OF FACT AND CONCLUSIONS OF LAW

Plaintiff having filed a Complaint praying for a temporary restraining order, for a preliminary injunction, and for a permanent injunction; and the Court having granted the prayer for a temporary restraining order; and the defendants having appeared and answered; and the Court having denied the prayer for a preliminary injunction; and the cause having come on for trial on the plaintiff's prayer for a permanent injunction; and this cause having been consolidated for trial with U. S. vs. Hudson Products Co., et al., No. 10-391-HW Civil; and the parties having offered documentary evidence by stipulation; the Court now makes the following Findings of Fact and Conclusions of Law as required by Rule 52(a) of the Federal Rules of Civil Procedure:

Findings of Fact

(1) Defendant El-O-Pathic Pharmacy, a corporation, was dissolved on September 7, 1949, and is no longer in existence.

(2) Defendant Vita Pharmacals, Inc., is a corporation organized under [152] the laws of California. It has its principal place of business at 1109½ No. Western Avenue, Hollywood, California. It has purchased all of the assets and liabilities of said El-O-Pathic Pharmacy.

(3) Defendant Martin A. Clemens is the general manager of defendant Vita Pharmacals, Inc., and is primarily responsible for the policies and activities of said corporation.

(4) For some years, defendant Martin A. Clemens has been engaged in the interstate and intrastate distribution of male and female hormone drugs, conducting such business at first in his own name and then as general manager of corporations such as El-O-Pathic Pharmacy and Vita Pharmacals, Inc.

(5) Defendant Clemens and defendant El-O-Pathic Pharmacy were convicted in this Court on July 13, 1949, in Docket No. 20596-Criminal, of violating the Federal Food, Drug, and Cosmetic Act by reason of their distribution of misbranded male and female hormone drugs.

(6) There is no evidence that defendants have continued the distribution of female hormone drugs since July 13, 1949.

(7) Subsequent to July 13, 1949, defendants Clemens and Vita Pharmacals, Inc., have changed the labeling of the male hormone drugs which they distribute. They will probably continue the interstate and intrastate distribution of said drugs as presently labeled on a large scale unless restrained from so doing by this Court.

(8) Four of the male hormone drugs which defendants sell over-the-counter and on mail order consist of:

(a) Methyl testosterone tablets (10 milligrams)

(b) Methyl testosterone tablets (25 milligrams)

(c) Methyl testosterone linguets (5 milligrams)

(d) Methyl testosterone linguets (10 milligrams)

These drugs are sold in quantities ranging from 50 tablets per package to 1000 tablets per package.

(9) Said drugs are manufactured by Ciba Pharmaceutical Products, Inc., Summit, New Jersey; by Roche-Organon, Inc., Nutley, New Jersey; and by Schering Corporation, Bloomfield, New Jersey. Said drugs are shipped interstate by the [153] manufacturers to defendant Vita Pharmacals, Inc.

(10) During the interstate movement of said drugs from said manufacturers to said defendant Vita Pharmacals, Inc., the labeling of each of said drugs bears the legend: "Caution: To be dispensed only by or on prescription of a physician."

(11) Defendants Clemens and Vita Pharmacals, Inc., however, do not require a physician's prescription in their resale of said drugs.

(12) Defendants Clemens and Vita Pharmacals, Inc., repackage and relabel said drugs after receiving them from the manufacturers. The labels which said defendants use are those which comprise Exhibit B of the Affidavit of Martin A. Clemens.

(13) Defendants Clemens and Vita Pharmacals, Inc., also ship interstate on mail order a male hormone drug consisting of methyl testosterone combined with Vitamin B-1 in linguet form. Said drug is labeled as set forth in Paragraph 13(a) of the Amendment to Complaint for Injunction.

(14) The labeling of each of the male hormone drugs which said defendants distribute uses the word "physician" four times in such phrases as "under supervision of a physician." Said labeling includes a statement that a physician should be consulted before taking testosterone.

(15) The labeling of each of said drugs contains adequate directions for use.

(16) The labeling of each of said drugs contains adequate warnings.

(17) There is medical opinion on both sides as to whether there are ill effects from taking said drugs.

(18) Said drugs are not dangerous to health when taken as directed in the labeling.

(19) The plaintiff has not sustained its burden of proof with respect to its allegations in issue.

(20) The plaintiff has not established that a 5 milligram linguet of methyl testosterone taken once daily is ineffective in the treatment of male hormone deficiency. [154]

Conclusions of Law

(1) This Court has jurisdiction over the subject matter of this cause and the parties thereto.

(2) The Complaint, as amended, is dismissed as to defendant El-O-Pathic Pharmacy, a corporation, since said defendant has been dissolved and is no longer in existence.

(3) The male hormone drugs distributed by defendants Martin A. Clemens and Vita Pharmacals, Inc., are not misbranded within the meaning of 21 U.S.C. 352(f)(1) since the suggestion in the labeling of said drugs that they be taken in consultation with a physician constitutes adequate directions for use.

(4) The male hormone drugs distributed by said defendants are not misbranded within the meaning of 21 U.S.C. 352(f)(2) since the suggestion in the labeling of said drugs that they be taken in consultation with a physician constitutes adequate warning against use in those pathological conditions where their use may be dangerous to health.

(5) The male hormone drugs distributed by said defendants are not misbranded within the meaning of 21 U.S.C. 352(j) since said drugs are not dangerous to health when used in the dosage and with the frequency and duration recommended in the labeling if the drugs are taken as suggested in the labeling, namely, in consultation with a physician.

(6) The male hormone drugs [the 5 milligram methyl testosterone linguets, and the combination methyl testosterone and Vitamin B-1 linguets] dis-

tributed by said defendants are not misbranded within the meaning of 21 U.S.C. 352(a) since it has not been established that the daily intake of 5 milligrams of methyl testosterone in linguet form is ineffective in the treatment of male hormone deficiency.

(7) The plaintiff's prayer for a permanent injunction is denied.

Dated: May 22nd, 1950.

/s/ HARRY C. WESTOVER,
United States District Judge.

Affidavit of Service by Mail Attached.

[Endorsed]: Filed May 22, 1950. [155]

In the United States District Court, in and for the
Southern District of California, Central Division

No. 10,266-HW Civil

UNITED STATES OF AMERICA,
Plaintiff,

vs.

EL-O-PATHIC PHARMACY, a Corporation,
MARTIN A. CLEMENS, an Individual, and
VITA PHARMACALS, INC, a Corporation,
Defendants.

JUDGMENT

Plaintiff having filed a Complaint praying for a

temporary restraining order, for a preliminary injunction, and for a permanent injunction; and the Court having granted the prayer for a temporary restraining order; and the defendants having appeared and answered; and the Court having denied the prayer for a preliminary injunction; and the cause having come on for trial on the plaintiff's prayer for a permanent injunction; and this cause having been consolidated for trial with United States v. Hudson Products Co., et al., No. 10,391-HW Civil; and the parties having offered documentary evidence by stipulation; and the Court having filed Findings of Fact and Conclusions of Law as required by Rule 52(a) of the Federal Rules of Civil Procedure;

It Is Therefore Ordered, Adjudged, and Decreed that the plaintiff's prayer for a permanent injunction be, and is hereby denied, and that the Complaint for Injunction be, and is hereby, dismissed.

Dated: May 22, 1950.

/s/ HARRY C. WESTOVER,
U. S. District Court Judge.

Judgment entered May 22, 1950.

[Endorsed]: Filed May 22, 1950. [157]

In the United States District Court, for the
Southern District of California, Central Division

Civil Action No. 10391-PH

UNITED STATES OF AMERICA,

Plaintiff,

vs.

HUDSON PRODUCTS COMPANY, a Corpora-
tion, and Its Subsidiary Firm Doing Business
Under the Fictitious Name and Style, MAY-
WOOD PHARMACAL COMPANY, and
ALLEN H. PARKINSON, an Individual,
Defendants.

COMPLAINT FOR INJUNCTION

[21 U.S.C. 332(a), 331(a), 352(a),
352(f)(1) and (2)]

United States of America, plaintiff herein, by
and through James M. Carter, United States At-
torney for the Southern District of California,
Central Division, respectfully represents to this
Honorable Court as follows:

1. This proceeding is brought under section
302(a) of the Federal Food, Drug, and Cosmetic
Act [21 U.S.C. 332(a)], hereinafter referred to as
the "Act," specifically vesting jurisdiction in the
several United States District Courts to restrain
violations of section 301 of said Act [21 U.S.C. 331]
as hereinafter appears more fully.

2. The defendant, Hudson Products Company, is a corporation having its principal place of business at 1067 E. Anaheim Street, Long Beach, California. The Hudson Products Company also trades under the fictitious name and style of Maywood Pharmacal Company, 6912 Hollywood Boulevard, Hollywood, California; all [158] mail orders received by the Maywood Pharmacal Company are filled and mailed by Hudson Products Company. The defendant, Allen H. Parkinson, who resides in the County of Los Angeles, State of California, within the jurisdiction of this Honorable Court, is the president of said Hudson Products Company and is primarily responsible for the policies and activities of the firm.

3. Said Hudson Products Company, Maywood Pharmacal Company, and Allen H. Parkinson, are distributors of certain male and female hormone drugs; the male hormone drugs consist of methyl testosterone tablets (10 milligrams), methyl testosterone linguets (5 milligrams), methyl testosterone linguets combined with a small amount of vitamin B-1 (daily dosage of testosterone when taken as directed being 5 milligrams); the female hormone drugs consist of tablets containing 0.1 milligram alpha-estradiol.

4. In newspaper and magazine advertising, defendants represent and suggest that male hormones are efficacious for the treatment of alleged symptoms of middle age such as nervousness, tiredness, and uncertainty about the future; that the adminis-

tration of male hormones causes the years after 40 to be the best time of a man's life; and that the administration of male hormones is effective in overcoming sexual impotence and in causing sexual rejuvenation.

5. Said defendants are also circularizing former customers, offering a revised formula containing methyl testosterone with vitamin B-1 in linguet form. Said defendants are also circularizing druggists in the State of California and other states offering Hudson Hormones on a wholesale basis. The circular describes the products offered as methyl testosterone tablets, both with and without vitamin B-1; it states that the Hudson Products Company, Inc., is launching an intensive national advertising campaign, telling every man and woman they can buy Hudson Hormones at their favorite drug store; it further states that these drugs are to be sold "over-the-counter"—e.g., without a physician's prescription.

6. The methyl testosterone linguets are offered for sale and shipped in interstate commerce under the following labeling: [159]

Copy of Carton Label

[Front and Rear Panel Identical]

30 5 mg. each

Hudson Hormone Tablets for Men

Each tablet contains 5 mg. Methyl Testosterone.
(For absorption under the tongue or inside the

cheek.) For use when Methyl Testosterone is indicated for relief of symptoms of Male Hormone deficiency.

Hudson Products Co.

Long Beach 5, Calif.

5 Mg. Regular Strength

[Side Panels—identical]

Hudson Hormone Tablets

This is a new and more effective male hormone tablet. It is not swallowed, but is held in the mouth between the teeth and the cheek until the hormone is completely absorbed by the cheek tissues and goes directly into the blood stream. This method by-passes the liver, where any hormone that is taken orally is partially deactivated. This tablet is specially made to dissolve slowly (about 30 minutes).

Notice: This new tablet is 2 to 3 times more effective than hormone tablets that are taken orally.

Copy of Bottle Label

[Side Panel]

Notice: It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted, [160] since testosterone will not aid or relieve symptoms not associated with male hormone deficiency.

Suggested Dosage: One tablet daily shortly before retiring. Tablets should be held between gum and

cheek, or under tongue, and allowed to dissolve slowly so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from 3 to 6 months, under supervision of a physician.

[Front Panel]

30 Tablets

5 mg. each

Hudson Hormones for Men 5 mg.

Regular Strength Methyl Testosterone

Hudson Products Co.

Long Beach 5, California

Distributors

[Side Panel]

Directions: For use by adult males mildly deficient in male hormone when small dosages of male hormone are prescribed or recommended by a physician for palliative relief of such symptoms.

Caution: The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate or by anyone with cardiovascular disease, defects of spermatogenesis, sterility whether absolute or partial, [161] or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed. Children and young adults must not use except

under constant direct supervision of a physician.

7. The defendants also offer for sale and ship in interstate commerce linguets containing methyl testosterone and vitamin B-1 under the following labeling:

Copy of Carton Label

[Front Panel]

30 Tablets

Male Hormone (Methyl Testosterone)

Combined With Vitamin B-1

•
Open
Here
•

Directions: For use when Methyl Testosterone is indicated for palliative relief of symptoms of male hormone deficiency by those males mildly deficient in male hormone and where small dosages of hormone are indicated. Daily recommended intake of one light and one dark (higher potency) tablet provides 5 milligrams of Methyl Testosterone and 3 milligrams of Vitamin B-1 (Thiamin Hydrochloride) in a specially prepared base for sublingual use. See instructions on back. [162]

Maywood Pharmacal Company

[Back Panel]

Double-Your-Money-Back Agreement

If you use Maywood Hormones as directed and are not fully satisfied with the results you have ob-

tained, return the box and the unused tablets to Maywood Pharmacal Company and we will cheerfully refund double your money.

Suggested Dosage: One light tablet upon arising before breakfast, and one dark tablet shortly before retiring. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosages can be extended from 3 to 6 months, under supervision of a physician.

Caution: The male hormone should not be taken by anyone with carminoma of the prostate, or urinary retention possibly due to carcinoma of the prostate, or by anyone with cardio-vascular disease, or debilitation due to disease. Take only as directed. Adolescents must not use except under constant direct supervision of a physician.

[Top Panel]

The hormones in this package are of purest laboratory-controlled potency. Maywood Hormones may be obtained in 30, 60 and 180-tablet packages.

Distributed by
Maywood Pharmacal Company
6912 Hollywood Blvd., Hollywood 28, Calif.

[Bottom Panel]

Methyl Testosterone combined with Vitamin B-1
Maywood Pharmacal Company

Copy of Label Wrapped Around
Pasteboard Carton

[Front Panel]

30 Tablets

Male Hormone (Methyl Testosterone)
Combined With Vitamin B-1

°
Open
Here
°

Directions: For use by adult males mildly deficient in male hormone when small dosages of male hormone are prescribed or recommended by a physician for palliative relief of such symptoms.

Daily recommended intake of one light and one dark (higher potency) tablet provides 5 milligrams of Methyl Testosterone and 3 milligrams of Vitamin B-1 (Thiamin Hydrochloride) in a specially prepared base for sublingual use. See instructions on back.

Maywood Pharmacal Company

[Side Panel]

Pull out cellophane tape and tear off individual "Packet-Pak" at perforation. Each packet contains average daily dose of one light (morning) and one dark (evening) tablet. Tear off corner of

packet to extract morning tablet, then cellophane can be folded to protect evening tablet until taken.

[Rear Panel]

Suggested Dosage:

One light tablet upon arising before breakfast, and one dark tablet shortly before retiring. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from 3 to 6 months, under supervision of a physician.

Caution: The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate or by anyone with cardiovascular disease, defects of spermatogenesis, sterility whether absolute or partial, or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed. Children and young adults must not use except under constant direct supervision of a physician.

[Side Panel]

It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted, since testosterone will not aid or relieve

symptoms not associated with male hormone deficiency. [165]

8. Defendants violate section 301(a) of the Act [21 U.S.C. 331(a)] by causing the introduction into interstate commerce of methyl testosterone linguets, labeled as described in paragraphs 6 and 7, which are misbranded in the following respects:

(a) Within the meaning of section 502(a) of the Act [21 U.S.C. 352(a)] in that the labeling is false and misleading, since it represents and suggests that the suggested daily dosage is efficacious for use in the treatment of male hormone deficiency, whereas the suggested daily dosage would be entirely ineffective for that purpose;

(b) Within the meaning of section 502(f) (1) of the Act [21 U.S.C. 352 (f)(1)] in that the labeling of said linguets fails to bear adequate directions for use in all conditions for which said linguets are prescribed, recommended, and suggested in their labeling and their advertising matter disseminated and sponsored by the defendants;

(c) Within the meaning of section 502(f) (2) of the Act [21 U.S.C. 352 (f)(2)] in that the labeling of said linguets fails to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, in such manner and form as are necessary for the protection of the user, since the technical medical terminology in which the cautionary statement on the labeling

is couched is inadequate to warn the ordinary lay user that its use may accelerate the malignant growth of cancer of the prostate gland or may cause sterility.

9. With respect to the methyl testosterone tablets, it is likely that the defendants will cause the same violation of section 301(a) of the Act [21 U.S.C. 331(a)] as they are causing with respect to the methyl testosterone linguets, (as described in paragraph 8(a), (b), and (c) above), since the defendants have in the past sold these products freely in interstate commerce, without a physician's prescription, and without adequate warnings. [166]

10. With respect to the alpha-estradiol preparations, it is likely that the defendants will cause the same or similar violations of section 301(a) of the Act [21 U.S.C. 331(a)] as they are causing with respect to the methyl testosterone linguets (as described in paragraphs 8(a), (b), and (c) above), since the unrestricted use of alpha-estradiol preparations by women may accelerate the malignant growth of cancer of the breast, cervix, and uterus, and may cause injury to the female generative system; and since the defendants have in the past sold these products freely, without a physician's prescription, and without adequate warnings.

11. In the case of the *United States v. Allen H. Parkinson*, an individual trading as Hudson Products Company, No. 20642-Criminal, this Court on July 13, 1949, convicted Allen H. Parkinson, an individual, trading as Hudson Products Company,

for the distribution of misbranded male and female hormones in violation of the Act. The hormones there involved included methyl testosterone tablets and alpha-estradiol tablets. In announcing judgment, the Court stated it was convinced beyond a reasonable doubt that these hormone preparations constituted not merely a potential danger but also an actual danger to health when used indiscriminately by the lay person. The Court also stated that the therapeutic claims which the defendant made for these products far exceeded the benefits that could be derived from them.

12. In less than a month after the aforesaid conviction, the defendants embarked upon a widespread promotion of the methyl testosterone-containing products in essentially the same misbranded condition as were the products involved in the criminal prosecution. The revised labelings and the marketing of methyl testosterone linguets in combination with vitamin B-1 for practical purposes constitute a continuation of the business declared illegal by this Court in the aforesaid criminal prosecution.

13. The plaintiff is informed and believes that unless restrained by the Court the defendants will continue to introduce and deliver for introduction into interstate commerce the said articles of drug misbranded in the manner aforesaid.

Wherefore, plaintiff prays: [167]

That the defendants, Hudson Products Company, a corporation, its subsidiary firm doing business under the fictitious name and style, Maywood Phar-

macal Company, and Allen H. Parkinson, and each and all of their officers, agents, servants, employees, and attorneys, and all persons in active concert or participation with any of them, be perpetually enjoined from directly or indirectly causing to be introduced or delivered for introduction into interstate commerce, in violation of section 301(a) of the Act [U.S.C. 331(a)] the articles of drug, hereinafter described, misbranded within the meaning of sections 502(a), 502(f)(1), or 502(f)(2) of the Act [21 U.S.C. 352(a), 352(f)(1), or 352(f)(2)].

That an Order be made and entered directing the defendants to show cause at a time and place to be designated in such order why they should not be enjoined and restrained as herein prayed during the pendency of this action; that upon the hearing of said order to show cause, a Preliminary Injunction be granted restraining the defendants as herein prayed during the pendency of this action;

That the plaintiff be given judgment for its costs herein and for such other and further relief as to the Court may seem just and proper.

JAMES M. CARTER,
United States Attorney.

CLYDE C. DOWNING,
Assistant U. S. Attorney
Chief, Civil Division.

/s/ GEORGE E. DANIELSON,
Assistant U. S. Attorney.

[Title of District Court and Cause No. 10391-PH.]

ORDER TO SHOW CAUSE

Upon the Complaint of the Plaintiff, United States of America, filed in the above-entitled case on September 29, 1949, and good cause appearing therefor,

It Is Hereby Ordered that the defendants, Hudson Products Company, Maywood Pharmacal Company, and Allen H. Parkinson, be and appear before this Court in the Courtroom of Judge Peirson M. Hall, United States Post Office and Courthouse Building, 312 North Spring Street, Los Angeles, California, at the hour of 2:00 p.m., on the 24th day of October, 1949, then and there to show cause, if any there be, why a preliminary injunction should not be issued enjoining and restraining said defendants, during the pendency of this action, from further violations of the Federal Food, Drug, and Cosmetic Act, as prayed in said Complaint.

And It Is Further Ordered that the service of a copy of this Order by the United States Marshal, or one of his deputies, together with a copy of the said Complaint, be made upon each of the said defendants on or before the 10th day of October, 1949, and that the same shall be deemed sufficient service of said Order and Complaint.

Dated: September 29, 1949.

/s/ PAUL J. McCORMICK,

United States District Judge.

[Endorsed]: Filed September 29, 1949. [170]

[Title of District Court and Cause No. 10391-PH
Civil.]

STIPULATION REGARDING
MEDICAL AFFIDAVITS

It is stipulated by and between the plaintiff, United States of America, and the defendants, Hudson Products Company, Maywood Pharmacal Company, and Allen H. Parkinson, through their respective counsel, that the affidavits of Dr. Thienes, Dr. Belt, and Dr. Macdonald, heretofore filed by the plaintiff in this Court in the case of United States v. El-O-Pathic Pharmacy, et al., No. 10266-PH, shall be deemed also to have been filed in the instant proceeding.

A certified copy of each of said affidavits is attached hereto.

JAMES M. CARTER,
United States Attorney,

CLYDE C. DOWNING,
Assistant U. S. Attorney
Chief, Civil Division,

/s/ GEORGE E. DANIELSON,
Assistant U. S. Attorney,
Attorneys for Plaintiff.

/s/ EUGENE M. ELSON,
Attorney for Defendants.

[Endorsed]: Filed October 20, 1949. [174]

[Title of District Court and Cause No. 10391-PH Civil.]

AFFIDAVIT OF ROBERT S. ROE

United States of America,
Southern District of California—ss.

Robert S. Roe, being first duly sworn, deposes and says that he is Chief, Los Angeles District, Food and Drug Administration, Federal Security Agency, and that the following facts are derived from his personal knowledge and from the official records of the Food and Drug Administration in his possession:

(1) On July 13, 1949, Allen H. Parkinson, an individual, trading as Hudson Products Company, Long Beach, California, was convicted in this Court of violating the Federal Food, Drug, and Cosmetic Act. (No. 20652-Criminal.) The substance of the charges upon which the defendant was convicted was the indiscriminate sale of dangerous drugs for lay use, together with the making of extravagant therapeutic claims for those drugs. The drugs involved in that case were male and female sex hormone preparations including methyl testosterone tablets and alpha-estradiol preparations.

(2) Defendant Allen H. Parkinson is now continuing a large scale business in male and female sex hormones. Mr. Parkinson is the President of the Hudson Products Company, a corporation do-

ing business in Long Beach, California, and is responsible for the policies and activities of that company as well as of the Maywood Pharmacal Company, which is a fictitious name under [171] which the Hudson Products Company does some of its business. The practice of these defendants has been to promote a widespread interstate distribution of the above-described drugs by creating the impression through labeling and newspaper advertising that such drugs have miraculous powers of sexual rejuvenation for men over 40, and that they will alleviate disease conditions in women caused by change of life. In selling these products direct to laymen by mail-order purchases, said defendants do not require a physician's prescription.

(3) The current methods of distribution adopted by the defendants with respect to methyl testosterone linguets subsequent to the conviction of Allen H. Parkinson are as described in paragraphs 4, 5, 6, and 7 of the Complaint filed in the instant case.

(4) Defendants are in the midst of unloading a large quantity of these drugs without prescription, upon the public. Defendants are thereby now caus-

ing immediate and irreparable injury, loss, and danger to the public for the reasons stated in the affidavits of Dr. Thienes, Dr. Belt, and Dr. Macdonald.

/s/ ROBERT S. ROE,

Chief, Los Angeles District, Food and Drug Administration.

Subscribed and sworn to before me, this 20th day of October, 1949.

EDMUND L. SMITH,

Clerk, U. S. District Court, Southern District of California.

By /s/ WM. A. WHITE,

Deputy.

Affidavit of Service by Mail Attached.

[Endorsed]: Filed October 20, 1949. [172]

[Title of District Court and Cause No. 10391-PH.]

ANSWER OF HUDSON PRODUCTS COMPANY, A CORPORATION; HUDSON PRODUCTS COMPANY, A CORPORATION DOING BUSINESS AS MAYWOOD PHARMACAL COMPANY, AND ALLEN H. PARKINSON, AN INDIVIDUAL

The defendants, Hudson Products Company, a corporation; Hudson Products Company, a corpora-

tion doing business under the fictitious firm name of Maywood Pharmacal Company, and Allen H. Parkinson, an individual, by way of Answer to the Complaint for Injunction filed herein admit, deny and allege as follows:

I.

Answering the allegations of Paragraph 3 of said Complaint these answering defendants admit that Hudson Products Company, a corporation, and Hudson Products Company, a corporation doing business under the fictitious firm name of Maywood Pharmacal Company, are distributors of certain male hormone drugs; that said male hormone drugs consist of methyl testosterone linguets [183] containing 5-milligrams of methyl testosterone and methyl testosterone linguets containing 5-milligrams of methyl testosterone and a small amount of Vitamin B₁. These answering defendants deny generally and specifically each and every other allegation contained in said Paragraph, and in this connection deny that said defendants or any of them have at any time or at all sold, offered for sale or distributed in interstate or intrastate commerce any female hormone drugs of the kind and character described in said Paragraph or otherwise since on or about July 13, 1949; and deny that they, or any of them, intend to sell, offer for sale or distribute female hormone drugs of the kind or character described in said Paragraph in interstate or intrastate commerce.

II.

Deny generally and specifically each and every allegation contained in Paragraph 4 of said Complaint.

III.

Answering the allegations of Paragraph 5 of said Complaint defendants admit that Hudson Products Company, a corporation doing business under the fictitious firm name of Maywood Pharmacal Company, has since on or about July 13, 1949, circularized former customers of Hudson Products Company, a corporation, offering a revised formula containing methyl testosterone with Vitamin B₁ in linguet form. Defendants attach hereto and incorporate herein by reference as though fully set forth one of said circulars and mark the same as Exhibit "A" hereto. Defendants admit that defendant Hudson Products Company, a corporation, is circularizing and since on or about July 13, 1949, has circularized druggists in the State of California and other states offering Hudson hormones on a wholesale basis. Defendants allege that said last named circulars, among other things, describe the products offered, as methyl testosterone tablets, both with and without Vitamin B₁, and that among other things said circular states [184] "Hudson Products Company, Inc., is launching an intensive national advertising campaign, telling every man and woman they can buy Hudson Hormones at their favorite drugstore"; and that said circular, among other things, states that "At last, the first Hormones to be labeled for over-the-counter sale." Defendants

attach hereto and incorporate herein by reference as though fully set forth, one of last named circulars and mark the same as Exhibit "B" hereto.

Defendants deny generally and specifically each and every other allegation contained in said Paragraph 5, except insofar as the same is expressly admitted herein.

IV.

Answering the allegations of Paragraph 6 of said Complaint defendants admit that Hudson Products Company, a corporation, did until on or about August 26, 1949, offer for sale and ship in interstate commerce methyl testosterone tablets for sublingual use labeled on the carton and on the bottle as alleged in Paragraph 6 of said Complaint. On or about August 26, 1949, defendant Hudson Products Company, a corporation, in lieu of the labeling described in Paragraph 6 of said Complaint composed a new package with the same labeling described in Paragraph 6 of said Complaint, adding to said product Vitamin B₁, and that said product as relabeled has since said date been offered for sale and shipped and is now offered for sale and shipped in interstate commerce by Hudson Products Company, a corporation doing business under the fictitious firm name of Maywood Pharmacal Company. Said carton does not contain a bottle of said tablets as formerly distributed, but contains cellophane strips containing tablets of methyl testosterone combined with Vitamin B₁. A true and correct copy of the carton label so used by Hudson

Products Company, a corporation, prior to August 26, 1949, is attached hereto, incorporated by reference herein as though fully set forth and marked Exhibit "C." The bottle label so used by Hudson Products Company, [185] a corporation, prior to August 26, 1949, is attached hereto, incorporated by reference herein as though fully set forth and marked Exhibit "D." The label used by Hudson Products Company, a corporation doing business under the fictitious name of Maywood Pharmacal Company, since August 26, 1949, is attached hereto, incorporated by reference herein as though fully set forth and marked Exhibit "E." Except as otherwise expressly admitted herein, defendants and each of them deny generally and specifically each and every other allegation contained in said Paragraph 6.

V.

Answering the allegations of Paragraph 7 of said Complaint defendants admit that defendants Hudson Products Company, a corporation doing business under the fictitious firm name of Maywood Pharmacal Company, do now offer for sale and ship in interstate commerce methyl testosterone tablets containing Vitamin B₁ for sublingual use, labeled as described in said Paragraph 7. Defendants allege that the package or carton in which said product is so shipped, together with the labeling appearing thereon is the same as that contained on Exhibit "E" hereto. Except as otherwise expressly admitted herein, defendants and each of them deny generally and specifically each and every other allegation contained in said Paragraph 7.

VI.

Answering the allegations of Paragraph 8 of said Complaint defendants and each of them deny generally and specifically each and every allegation contained therein.

VII.

Answering the allegations of Paragraph 9 of said Complaint defendants and each of them deny generally and specifically each and every allegation contained therein.

VIII.

Answering the allegations of Paragraph 10 of said [186] Complaint defendants and each of them deny generally and specifically each and every allegation contained in said Paragraph, and in this connection allege that defendants have not, nor have either of them, since on or about July 13, 1949, sold, offered for sale or shipped in interstate or intrastate commerce any of the female hormone drugs described in said Paragraph 10, or any of the other female hormone drugs; and that said defendants do not intend to sell, offer for sale, or ship in interstate or intrastate commerce any female hormone drugs of the kind or character described in said Paragraph.

IX.

Answering the allegations of Paragraph 11 of said Complaint these answering defendants admit that defendant Allen H. Parkinson, an individual, was convicted in the above-entitled Court in case No. 20642, Criminal, on July 13, 1949, of distributing

in interstate commerce male and female hormones misbranded in the Federal Food, Drug and Cosmetic Act. Admit that the hormones involved in said action included methyl testosterone and alpha-estradiol tablets. Deny that the Court in said action in announcing judgment stated the matters and things alleged in Paragraph 11 of the Complaint in this action, and in this connection allege that said Court stated in announcing judgment as follows:

“As to cases 20596, 20642 and 20608, from the evidence and the weight of the evidence I am convinced, beyond a reasonable doubt, that the indiscriminate distribution or dispensation for use of the drugs Testosterone, Methyl-testosterone, Non-Crystalline Estrone and Alpha Estradiol carried not only a potential but an actual danger of injury to some persons. I am also convinced from the evidence that these drugs do not, other than within a [187] restricted class of cases, produce many or any of the alleviatory and beneficial effects that the labeling given them by the defendants indicate and encourage readers to believe that they will generally produce.”

That said Court further stated, in announcing judgment, as follows:

“Now, it is my construction of those pamphlets, leaflets and circulars enclosed in the packages, by which delivery of sales were made, that they were designed to create a belief

that many persons are deficient in their natural testosterone and that by supplementing it with the drug called under various names, a synthetic testosterone, that much benefit could be derived by the user. I do not mean this to convey the impression that I think the defendants intended any fraud. They may, so far as I know, have been acting in full belief of the merits of the drugs for the purposes they recommended them.

“I don’t think there is anything further that I need say in the cases.”

X.

Answering the allegations of Paragraph 12 of said Complaint, defendants and each of them deny generally and specifically each and every allegation contained therein.

XI.

Answering the allegations of Paragraph 13 of said Complaint, defendants and each of them deny generally and specifically each and every allegation contained therein.

Wherefore, defendants and each of them pray that plaintiff [188] take nothing by its action and for such other and further relief as may be proper.

HOWLETT AND ELSON,

By /s/ EUGENE M. ELSON,

Attorneys for Defendants.

Exhibit A

Maywood Pharmacal Company
6912 Hollywood Boulevard, Hollywood 28,
California

Hormones and Vitamins, Controlled Purity,
Insured Safety

Dear Friend

Everybody seems to be talking about hormones these days.

Since the male hormone was discovered a few short years ago there has been a flood of literature on the subject. You've probably read some of the many magazine and newspaper stories or the best-selling book on the male hormone. All of them are fascinating to read, and much of what they say is true. The truth about hormones is more amazing and wonderful than any fiction.

Many people would rather believe rumors than find out the truth. There has been a lot of loose gossip about hormones, especially the male hormone, and we hope you haven't been taken in by false rumors and ill-informed talk. Any new medical discovery that offers so much promise to mankind is bound to be the subject of speculation and gossip.

As one of America's leading distributors of hormone products, we want you to know the truth. We don't want this great discovery to be the subject of snickers or back-room talk. We want the public to know what hormones really will do, and what they won't do, and we don't want anyone to

feel that hormones are an embarrassing or hush-hush topic.

You can find out the truth from a qualified physician who has kept up with the latest developments in hormone research. Then you can order a supply of hormones and give them a fair trial.

The newest Maywood formula combines the Male Hormone with Vitamin B-1 in tablets which are easy and pleasant to take. They are available in the convenient Pocket-Pak in 30, 60 and 180-tablet sizes, with full directions for use. Maywood Hormones are of strict laboratory-controlled potency, and their purity and safety are insured with a leading American insurance company for \$100,000.

Because we want you to find out for yourself what hormones can do, Maywood Hormones are sold under an unconditional double-your-money-back agreement which is printed on the enclosed order form. To order, simply fill out the form and return it in the enclosed postage-paid air-mail envelope. Your order will be rushed to you by return air mail.

Sincerely yours,

/s/ WALTER WESTON,

Maywood Pharmacal Company.

IDEAL
SHELF-STOCK
PACKAGE
you get...



QUANTITY	ITEM	RETAIL
1/4 DOZ.	Male Hormone with Vitamin B ₁ (Methyl Testosterone) 30 tablets, per pkg. \$1.85	\$5.55
1/4 DOZ.	Male Hormone (Methyl Testosterone) 30 tablets, per package \$1.60	\$4.80
1/4 DOZ.	Male Hormone with Vitamin B ₁ (Methyl Testosterone) 60 tablets, per pkg. \$3.50	\$10.50
1/4 DOZ.	Male Hormone (Methyl Testosterone) 60 tablets, per package \$3.00	\$9.00
1/4 DOZ.	Male Hormone with Vitamin B ₁ (Methyl Testosterone) 180 tablets, per pkg. \$29.45	\$28.35
1/4 DOZ.	Male Hormone (Methyl Testosterone) 180 tablets, per package \$7.95	\$23.85
		<hr/>
		\$82.05

"The undersigned hereby guarantees that no article listed herein is, when shipped by the undersigned, adulterated or misbranded within the meaning of the Federal Food, Drug and Cosmetic Act, to the extent said act is then effective and applicable, or an article which may not, under the provisions of section 404 or 405 of said act, be then introduced into state commerce."

retails at ...

YOUR COST... **\$54.73**

If your wholesaler
does not stock ...

MAIL ENCLOSED CARD TODAY!

HUDSON
HORMONES

Exhibit B—(Continued)

Hudson Products Company

Hormones and Vitamins

1067 East Anaheim Street

Long Beach 13, California

Telephone: Long Beach 7-2585

Dear Sir

Everybody's talking about hormones . . . hormones mean big volume and new profits to all druggists.

What are you doing about hormones?

Hormones are the hottest thing in pharmaceuticals today—they'll soon be bigger than vitamins ever where. There's been a flood of publicity, a best-selling book, dozens of national magazine articles, countless newspaper stories.

Thousands of men and women everywhere are interested in hormones—need hormones—want hormones. They'll buy them wherever they can get them.

Most people don't know where to get them!

That's why Hudson Products Co., Inc., is launching an intensive national advertising campaign, telling every man and woman they can buy Hudson Hormones at their favorite drugstore. Twenty-five million match books will be circulated in California alone . . . plus newspaper ads and tie-in mats.

Your customers will be looking for Hudson Hormones with added Vitamin B-1. If you don't stock them they'll look somewhere else.

Hudson Hormones sell themselves . . . they're packaged for counter display. Put them out in front and watch 'em move.

Hudson Hormones mean big money to you . . . steady repeat sales . . . new customers. They're a product you can promote!

Don't miss these hormone profits . . . don't wait for your competitors to beat you to the draw . . . call your wholesaler or mail the enclosed card.

Yours for faster profits,

/s/ JOHN HUDSON,

HUDSON PRODUCTS CO.,
INC.

Cable Address:

HUDPROCO

Reference:

Security-First National

Bank of Los Angeles,

Bixby Knolls Branch

Laboratory Controlled Potency - Nationally Known
Nationally Advertised

Exhibit B—(Continued)

Hudson Products Company

Hormones and Vitamins

1067 East Anaheim Street

Long Beach 13, California

Telephone: Long Beach 7-2585

Dear Sir

Everybody's talking about hormones . . . hormones mean big volume and new profits to all druggists.

What are you doing about hormones?

Hormones are the hottest thing in pharmaceuticals today—they'll soon be bigger than vitamins ever where. There's been a flood of publicity, a best-selling book, dozens of national magazine articles, countless newspaper stories.

Thousands of men and women everywhere are interested in hormones—need hormones—want hormones. They'll buy them wherever they can get them.

Most people don't know where to get them!

That's why Hudson Products Co., Inc., is launching an intensive national advertising campaign, telling every man and woman they can buy Hudson Hormones at their favorite drugstore. Twenty-five million match books will be circulated in California alone . . . plus newspaper ads and tie-in mats.

Your customers will be looking for Hudson Hormones with added Vitamin B-1. If you don't stock them they'll look somewhere else.

Hudson Hormones sell themselves . . . they're packaged for counter display. Put them out in front and watch 'em move.

Hudson Hormones mean big money to you . . . steady repeat sales . . . new customers. They're a product you can promote!

Don't miss these hormone profits . . . don't wait for your competitors to beat you to the draw . . . call your wholesaler or mail the enclosed card.

Yours for faster profits,

/s/ JOHN HUDSON,

HUDSON PRODUCTS CO.,
INC.

Cable Address:

HUDPROCO

Reference:

Security-First National

Bank of Los Angeles,

Bixby Knolls Branch

Laboratory Controlled Potency - Nationally Known
Nationally Advertised

exit with

The hormones in this package are of purest laboratory - controlled potency. Maywood Hormones may be obtained in 30, 60 and 180-tablet packages.

30 TABLETS

MALE HORMONE
combined with **VITAMIN B₁**

It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore before taking testosterone a physician should be consulted, since testosterone will not aid or relieve symptoms not associated with male hormone deficiency.

DIRECTIONS: Follow directions on label. Adult males may take 1 tablet in milk 4 or 5 times a day when normal dosage of 1 or 2 tablets 4 or 5 times a day is not recommended. See label for directions for use by a physician or pharmacist. For relief of such symptoms.

Daily recommended inhalation of one light and one dark (higher potency) tablet provides 3 milligrams of methyl testosterone and 3 milligrams of vitamin D₃ (Thiamin Hydrochloride) in a specially prepared base for sublingual use. See instructions on back.

Pharmaceutical Company

Pull out cellophane tongue and tear off individual "Pouch-Pod" of perforation. Each packet contains average daily dose of ampicillin (200 mg) and light (insoluble) enteric coating. One day's (24 hr) dose of 400 mg is in each of seven packets. Tear off corner of packet to expose morning tablet; the cellophane can be folded to protect evening tablet until bedtime.

EXCESSIVE TOLATEL
One light eater up-
pinged below breast-
fast, and one day
later, shortly before
retiring, belatedly
beheld between
and cheek, or odd
tongue, and allow-
to dislodge slowly.
But he never
absorbed by mouth
disturb (even may I
swallowed while his
let it in mouth, but
not swallow table.
The maintenance of
age can be aided
from 3 to 6 months
under supervision of
physicians.

[illegible]

**METHYL
TESTOSTERONE**
combined with
VITAMIN B₁

THE END 'C'

Exhibit D

[Center]

[Box Label]

30 tablets

5 mg each

Hudson Hormones for Men

Regular Strength Methyl Testosterone

Hudson Products Co.

Long Beach 5, California

Distributors

[Left Side]

Notice: It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted, since testosterone will not aid or relieve symptoms not associated with male hormone deficiency.

Suggested Dosage: One tablet daily shortly before retiring. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from 3 to 6 months, under supervision of a physician.

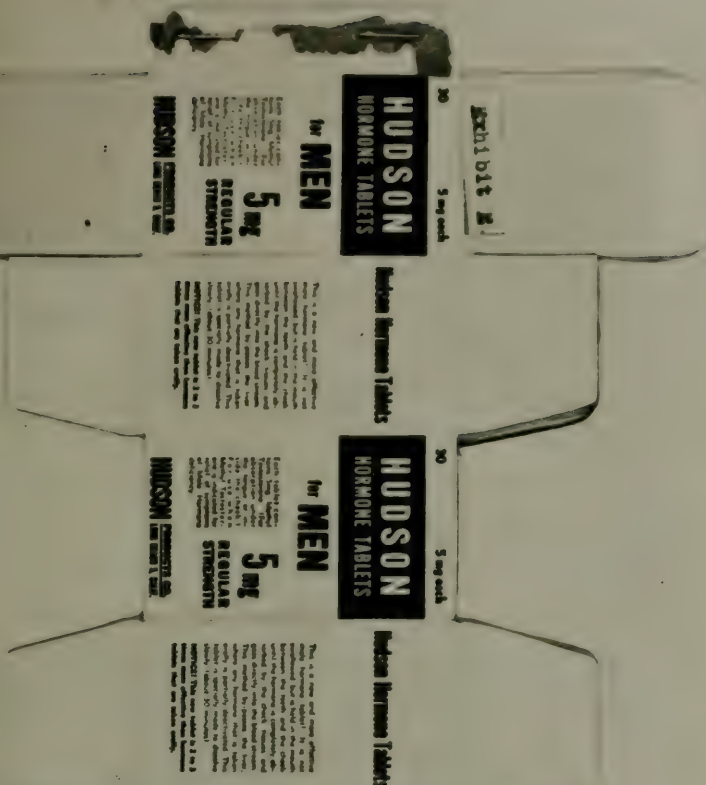
[Right Side]

Directions: For use by adult males mildly deficient in male hormone when small dosages of male hor-

mone are prescribed or recommended by a physician for palliative relief of such symptoms.

Caution: The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate or by anyone with cardiovascular disease, defects of spermatogenesis, sterility whether absolute or partial, or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed. Children and young adults must not use except under constant direct supervision of a physician.

EXHIBIT E



Duly verified.

[Endorsed]: Filed November 3, 1949.

[Title of District Court and Cause No. 10391-PH.]

AFFIDAVIT OF ALLEN H. PARKINSON

State of California,
County of Los Angeles—ss.

Allen H. Parkinson, being duly sworn, deposes and says:

That he makes this Affidavit in response to certain of the allegations contained in the Complaint for Injunction and the Affidavits of Clinton Hobart Thienes, M. D., Elmer Belt, M. D., Ian MacDonald, M. D., Robert S. Roe, each of which by stipulation of respective counsel herein are deemed to have been filed in this proceeding, and copies of which Affidavits are attached to said Stipulation and are all on file herein.

On or about April 8, 1949 there was filed an Information in the above-entitled Court, No. 20642 Criminal, in which affiant [196] Allen H. Parkinson was named as a defendant. In said Information it was charged that said Parkinson delivered for introduction into interstate commerce certain male hormone drugs and that the same were misbranded in violation of the Federal Food, Drug and Cosmetic Act. The product involved in each Count of said Information involving male hormone drugs, the particulars wherein said products were therein alleged to be misbranded, together with the Sections of the Federal Food, Drug and Cosmetic Act alleged to have been violated, were as follows:

Count I.

(a) Product:

Methyl testosterone tablets, 10 mg. each; oral dosage: 1 daily; in case of male sex hormone deficiency; 3 daily for 10 days, thereafter one per day;

(b) Particulars Wherein Misbranding
Was Alleged:

That accompanying said product in interstate commerce was a circular entitled "The Male Hormone." Affiant attaches hereto and marks as Exhibit "A" to this Affidavit a true and correct replica of the circular which accompanied said product.

(c) Violation Charged:

1. Section 502(a), Food, Drug and Cosmetic Act:
That the labeling consisting of said circular represented and suggested that said product:
 - a. was the true male sex hormone;
 - b. with respect to the average man in his late 40's it would stimulate growth and development of the sex organs;
 - c. that with respect to the average man in his late 40's it would stimulate growth and development of the male sex characteristics, such as
 - (1) distribution of hair
 - (2) muscular development
 - (3) depth of voice
 - d. would correct lack of sexual power and impotence;

- e. would relieve and postpone the many conditions associated with middle age;
- f. would improve the sense of well-being;
- g. would be efficacious in the treatment of
 - (1) flushes
 - (2) sweats
 - (3) chills
 - (4) impaired memory
 - (5) inability to concentrate on activities
tendency to evade them
 - (6) nervousness
 - (7) depression
 - (8) general weakness and lack of physical
strength

That the labeling represented by said circular further represented and suggested:

- a. that the use of said product would result in improved physical and mental work
- b. that the use of said product would exert a tonic action resulting in renewed vigor
- c. that said product would impart a better attitude toward social life
- d. that said drug would cause nervousness, exhaustion and melancholy to disappear.

That said representations were false and misleading [198] in that

- a. said drug would not accomplish the aforesaid purposes.

2. Section 502 (f) (1) Food, Drug and Cosmetic Act:
That said drug was further misbranded in that:
- a. the said labeling failed to bear adequate directions for use, in that the directions for use: "Dosage: 1 tablet daily. Important—in case of male sex hormone deficiency take 3 tablets daily for 10 days. After 10 day period take 1 tablet daily," on the labeling were not adequate directions for use.

Count II.

(a) Product:

Same as in Count I

(b) Particulars Wherein Misbranding
Was Alleged:

Same as Count I and, additionally, that accompanying said product was a leaflet entitled "The Story of Hormones." Affiant attaches hereto, incorporates by reference herein a true and correct replica of said leaflet "The Story of Hormones" as though fully set forth and marks the same as Exhibit "B" hereto.

(c) Violation Charged:

1. Section 502 (a), Food, Drug and Cosmetic Act;
That the pamphlet "Male Hormone" attached hereto as Exhibit "A" represented the matters and things hereto alleged with respect to Count I.
That the pamphlet "The Story of Hormones" represented and suggested

- a. that in the average man said product would

relieve and postpone the many conditions [199] formerly thought to be inevitable with middle age;

- b. that said product would be efficacious in:
 - (1) the treatment of nervous tension
 - (2) intense subjective nervousness and irritability
- c. that said product would be efficacious in the treatment of
 - (1) numbness in the extremities
 - (2) itching, prickling and tingling of the skin and waking up at night
 - (3) headaches.
- d. that said product would prevent a decrease in the ability to concentrate
- e. that said product would remedy faulty memory
- f. that said product would be efficacious in the treatment of depression and melancholia
- g. that said product would correct a lack of interest in social and business life
- h. that said product would correct a lack of mental concentration
- i. that said product would correct a feeling of inadequacy or impotency
- j. that said product would be efficacious in the treatment of
 - (1) hot flashes
 - (2) feelings of smothering and sweating and chilly, creepy sensations

- k. that said drug would prevent the user from tiring easily
- l. that said drug would prevent the user from gaining excessive weight [200]
- m. that said drug would be efficacious in the treatment of
 - (1) constipation
 - (2) vague digestive complaints
 - (3) precordial, angina pectoris-like pains
- n. that said drug would be efficacious in the treatment of urinary symptoms, such as
 - (1) frequency
 - (2) nocturia
 - (3) dribbling
 - (4) inability to start urinary stream
- o. that said drug would restore confidence in mental reactions and decisions
- p. that said drug would notably increase the users capacity for mental and physical work
- q. that said drug would increase potency and libido.

That said representations were false and misleading; and that drugs would not accomplish the aforesaid purposes.

2. Section 502 (f) (1), Food, Drug and Cosmetic Act; That said drug was further misbranded in that

- a. the labeling failed to bear adequate directions for use in that the directions "Dosage: 1 tablet daily. Important—in case of male sex hor-

mone deficiency take 3 tablets daily for 10 days. After 10 day period take 1 tablet daily" were not adequate directions for use.

Count IV charged: a shipment of female hormones, consisting of alpha-estradiol. An analysis of the charges contained in that Count are not set forth herein for the reason, as alleged [201] in the Answer of the defendants in the present action, said defendants have not shipped in interstate or intrastate commerce any female hormones since the date of Judgment in said Criminal action, July 13, 1949, and do not intend to ship in interstate or intrastate commerce such alpha-estradiol preparations.

No charge was made in said Information that adequate warnings against the use of said products in certain pathological conditions where its use might be dangerous were not contained in said label, and, in fact, on the leaflet attached hereto as Exhibit "A" appeared the statement:

"The male sex hormone should be carefully used by elderly men with cardiovascular disturbances and should not be used if there is any indication of cancer of the prostate."

On said pamphlet Exhibit "B" hereto "The Story of Hormones" was the warning language as follows:

"Although both male and female sex hormones are relatively safe to use as a rule, scientific tests prove that they should not be used by anyone suffering from cancer. Neither should they be used by persons suffering from

serious heart trouble. Also, hormone therapy should be used with caution by senile men in whom excessive stimulation of waning sex power may be physiologically undesirable.”

Recapitulating the aforesaid charges insofar as the same are material to this litigation, the charges of the Government were that the labeling of said products so shipped constituted a misbranding of said products for the following reasons:

1. That said labeling falsely misrepresented and suggested that said products would be efficacious in the treatment of the conditions enumerated [202] heretofore as to Count I in violation of Section 502(a) of the Food, Drug and Cosmetic Act.

2. That said labeling failed to bear adequate directions for use in that the directions contained on the label of the bottle were not adequate directions for use.

At the outset of the trial of said action, defendant Parkinson, and affiant herein, took the position and maintained the same throughout that the symptoms referred to in Exhibits “A” and “B” hereto would be relieved if the individual manifesting the same were suffering from a male hormone deficiency, and that said circulars, Exhibits “A” and “B” hereto, did no more than make such a representation, and did not represent that said male hormone products would be efficacious in the treatment or relief of said symptoms if they were caused by some condition other than a male hormone

deficiency. In connection therewith, at the outset of said action, defendant offered to the Court and served a copy thereof upon counsel, his argument in respect thereto entitled "Comparison of Information re Alleged Therapeutic Claims with Labeling Involved (the pamphlets 'Male Hormone' and 'The Story of Hormones')", and said documents so submitted became part of the files and records in said action.

With regard to the charge that the directions for use were inadequate the position of said defendant at the outset of said action and throughout the trial thereof was that said circulars, Exhibits "A" and "B" hereto, suggested the dosage set forth on said labeling and the use of said product only provided that the user was suffering from a male hormone deficiency, and that the information contained in said exhibits was sufficient to enable the average man to determine whether he was suffering from such a deficiency, at least, that he might use the product for a certain [203] period of time and if relieved could conclude that he was, in fact, suffering from such deficiency. That general practitioners, to whom the average individual suffering from such symptoms may go, will invariably prescribe methyl testosterone on more or less a trial and error basis to see whether or not the symptoms complained of are relieved upon use of the product and that if relieved will conclude that the individual was suffering from a male hormone deficiency; and that therefore, in substance, the method employed by the general practitioner in determining

whether methyl testosterone should be prescribed or recommended was and is the same as though the individual tried the product on his own behalf for a certain period of time.

Government Evidence in Support of the Aforesaid Charges

In support of the aforesaid charges, several medical witnesses were called to testify by the Government. References to the reporter's transcript in said criminal action will hereinafter be made for convenience in the event that it should develop that said reporter's transcript should be a part of the record in this case.

I.

Clinton A. Thienes, M.D.

So far as material to this case said witness testified as follows:

That assuming a man to be 50 years of age who complains of flushes, sweats, extreme nervousness, inability to concentrate, nocturia, and he goes to his doctor who is an average general practitioner, and no evidence of cancer of the prostate is diagnosed, he does not believe that the doctor would prescribe methyl testosterone for a period of time and wait and see whether the symptoms were relieved. In his opinion it would not be prescribed by the man's doctor unless there was evidence of the male [204] climacteric, and that the majority of general practitioners would require a laboratory

test as to the secretion of hormones from the testes before prescribing testosterone. (p. 42.)

A person who diagnoses his own condition as requiring testosterone probably will not be the type of person who needs it. (p. 62.) Symptoms such as inability to concentrate and irritability in males of approximately 50 years of age are present in conditions other than hormone deficiency. Most of those symptoms are due to something other than such deficiency. They are found in certain types of goiter, fatigue states, anxiety states; in tuberculosis one will find that type of symptom complex. Those conditions would not respond favorably to testosterone. (p. 66.) The only sure way that he knows to determine whether there is a hormone deficiency is by laboratory procedure—and an analysis of the urine. (p. 67.)

II.

Dr. Norris J. Heckel, M.D.

Professor of Urology, University of Illinois

He uses testosterone in urology only for the treatment of men who have a deficiency of the male sex hormone. (p. 159.) Such deficiency is found in endocrine disturbances, best illustrated by eunuchism and by men who have been castrated or whose testes have been injured. (p. 159-160.)

Generally, the symptoms of the male hormone deficiency are impotence, fatigues easily. Male hormone therapy is indicated to stimulate the growth

and development of the sex organs and male sex characteristics such as distribution of hair, muscular development and depth of voice, when that condition is caused by deficiency of the male sex hormone, best illustrated in the eunuchoid individual. (p. 162 and 165.)

Hormone therapy would not correct impotence in a man in his late 40's unless it were due to a male hormone deficiency. (p. 168, 169.) [205]

In his opinion, if a man had a male hormone deficiency, methyl testosterone would correct lack of sexual power and impotence, and would postpone the many conditions associated with middle age and improve the sense of well-being. If a man were suffering from such deficiency, methyl testosterone would constitute an adequate treatment for flushes, sweats and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness, and lack of physical strength. (p. 172, 173.)

However, there are many diseases that would produce those symptoms. But if a man were suffering from a male hormone deficiency, methyl testosterone would result in improved physical and mental work and would exert a tonic action resulting in renewed vigor and would impart a better attitude toward social life, and cause nervousness, exhaustion and melancholy to disappear. Those symptoms, however, are also symptoms of other diseases or conditions. (p. 174, 175.) A male hormone deficiency is determined first by a careful history, second, a careful physical examination,

and third, laboratory tests to aid in diagnosis such as the estimation of 17 kitosteroids in the urine, and by the estimation of the excretion of gonadotropins, also in the urine. (p. 176.)

There are no subjective symptoms by which he could correctly diagnose a male hormone deficiency, and the symptoms above described would not indicate, necessarily, a hormone deficiency. (p. 177.) Impotence is not an indication of male hormone deficiency for it may be due to a variety of causes such as syphilis or may be psycho-genic origin, worry, fatigue, mental strain. Impotence comes with age as a natural process. (p. 178.)

In his opinion, if a patient visited a general practitioner complaining of the several symptoms, nervousness, etc., etc., the doctor would make a careful examination of him to see if he could find out what produced the symptoms. He would conduct a complete [206] physical examination from head to foot. If that produced nothing, he would probably examine the urine for sugar. This might give him a clue to diabetes which would produce such symptoms. If he found no sugar, he would determine if there was albumin in the urine or whether the patient was suffering from Bright's Disease or some kidney disturbance. If nothing turned up then, he would take the patient's blood pressure. If that was normal and his urine negative, he would probably take a blood count to see whether the patient was suffering from anemia. There might be some indication that the patient had a gastro-intestinal disturbance, and an x-ray picture of the tract, or

colon, would be taken, or his basal metabolic test to discover whether there was some disturbance of the thyroid. If such doctor found nothing suspicious as the result of such examination, he might, but he shouldn't, suggest testosterone to the man for a period of 4 to 6 weeks to see if those symptoms were relieved. (p. 186-190.)

He, however, has never been able to make a diagnosis of the male climacteric. (p. 191.) There is no question but that in view of the hundreds of thousands of packages of testosterone sold during the year it is indicative of considerable benefit to many, many, many men. (p. 194-195.) He recognizes that some general practitioners are enthused about methyl testosterone and some object to it. (p. 216-217.) A doctor who is administering testosterone to a male patient keeps that patient under regular or periodic examination during treatment; the purpose being to detect any deleterious results that might occur. (p. 219-220.)

III.

Dr. Elmer Belt

Urologist and member of the Belt Urological Group.

(P. 224 and 372.)

He has personally seen or treated patients who have had adverse or injurious results from the administration of the male [207] hormone. (p. 227).

In the case of the ordinary practitioner to whom a patient goes because he wants a general physical

examination, the practitioner is obligated to put his finger in the rectum and carefully feel the prostate. (p. 233, 234.) There are many instances in which methyl testosterone is very valuable. The necessary precautions to its use are tests as follows: (1) rectal examination; (2) determination of the level of acid phosphatase in the bloodstream, and (3) other tests of recent origin. One test of the proteins of the blood which shows the presence of cancer or the absence of it, and another, a blood protein test. He feels that such precautions are a prerequisite to any testosterone therapy except in groups where cancer of the prostate is not liable to occur, and by that he means cases in which it is particularly valuable or the group of young individuals who show a definite endocrine deficiency in regard to testosterone and who need it in the normal process of their growth and development. (p. 246, 247.) By that he is referring to boys who had their testicles blown off during the war, (p. 390) and persons suffering from hypogonadism—persons whose testicles are not performing their proper function, meaning undeveloped testicles and undeveloped genitalia—a young individual whose testicles are not up to standard in size and function. (p. 391, 392.)

The acid phosphatase test, if one is set up for it, can be completed in a few minutes. The 17 ketosteroids test requires approximately a week to complete, and the blood test a very short time. The general practitioner is not equipped to make either of those tests and in fact, his office is not equipped

to make the 17 ketosteroids test, and he is having them made at the California Institute of Technology. (p. 395.) In a person who is apparently normal physically, the examination necessary to determine whether he is suffering from an endocrine deficiency might possibly be the [208] 17 ketosteroids test. (p. 248.) Such examinations require special training. There are no objective symptoms of a male hormone deficiency which a layman could recognize and actually use to diagnose such a condition. He might confuse almost anything with the loss of what he thought was his normal quantity of hormones. (p. 249.) After a careful examination of the patient and no indications of cancer of the prostate being present, it would still be dangerous or conducive to the development of cancer of the prostate for the person to take testosterone. (p. 251-253.)

In his opinion, if a man 45 to 50 years of age visited a general practitioner and complained of sweats, nervousness, did not remember things as he used to, couldn't concentrate on activities, had a tendency to evade them, and the doctor was of the opinion, after learning of these symptoms that testosterone might be of benefit to the patient, he, the doctor, would, before prescribing testosterone, in the first place, think—think about the problem, and if he thought about it very much he probably wouldn't prescribe testosterone for those symptoms because they do not indicate hypogonadism and it is virtually only in hypogonadism that testosterone is effective. (p. 383, 384.) A very careful analysis of

the problem would be needed for that patient and he would be very apt to get it at the hands of an alert general practitioner. (p. 385.) It would be a very loose method of detecting the man's trouble for the general practitioner to prescribe testosterone to such a patient for a period of 3 to 4 weeks to see whether the man had been relieved, for it the doctor really thought about the problem, got down to business and studied it, he would be concerned first about the psychic factors in the individual and whether he was overworked and trouble. (p. 385.) Before prescribing testosterone the general practitioner would certainly make a rectal examination and feel the prostate. As to the blood and urine tests, there would be no blood tests that such [209] doctor need do, unless he wished to do the acid and alkaline phosphatase tests. The urine test would not show him anything unless he wished to take the time to give the 17 ketosteroids test. (p. 385-386.) If he really wanted to find out whether the man had a hormone deficiency, he would give such a test, as well as acid phosphatase test, for cancer of the prostate, (p. 386) and if he used testosterone, then he would see that the symptoms were not relieved. (p. 387.)

The problem of hormone deficiency is the specialty of the general practitioner. The middle aged man who is tired and worn-out and who has come to the doctor for some help is the general practitioner's "meat." (p. 388.)

In the case of the individual who visits the general practitioner who gives him a rectal examination and finds nothing suspicious and prescribes methyl

testosterone, and the patient has the prescription filled, that patient can go back to a drug store as often as he wishes and have that prescription refilled without going to that doctor or to any other doctor and having a new prescription made up each time he wants testosterone. In fact, he doesn't have to have a prescription in the first place. (p. 398.) He can go back and have it refilled as often as he wants without seeing another doctor. (p. 399.)

What he is pleading for in this case is that the requirement be made that the product methyl testosterone be sold only on prescription. (p. 400.)

He does not think that the male has any climacteric, and he believes that most careful observers are of the same opinion. However, that is not an opinion that is universally shared by the profession. (p. 407.)

If the patient comes to him referred by another doctor, he always allows the other doctor the benefit of whatever doubt might exist in his mind, and his tendency is to go on with the [210] original treatment the other doctor has established until he can discuss the problem with him. (p. 436-437.)

IV.

Dr. Charles Huggins, M.D.

Professor of Urology, University of Chicago.

Since 1938 their work has been almost exclusively related to the male hormone and its reaction in normal and cancerous individuals. (p. 256-258.) He does not think that a male hormone deficiency

occurs in quasi-normal individuals—persons who are not hypogonads or who have not been castrated. (p. 260.) He denies that methyl testosterone would have any effect upon the conditions enumerated in the Information. These symptoms are not symptoms of a person who is deficient in male hormones. (p. 272-275.) Because of the toxic effects of the male hormone, he thinks that testosterone should always be administered under the supervision of somebody with some knowledge of such matters. (p. 277.)

In his opinion, if an individual complained to a general practitioner—an all around family doctor—of the symptoms referred to in the Information, some would prescribe methyl testosterone for a period of 4 to 6 weeks, and see whether the symptoms were relieved without going through the elaborate tests described by him—such as blood tests, etc.—but some doctors would not, and he thinks that very few informed physicians would prescribe it under those circumstances. (p. 292.) He doesn't think that the average physician would recognize the symptoms referred to as an indication for sex hormones. The blood test he referred to can only be done in well-established hospitals. (p. 294.) Listlessness, lack of memory, as described in the Information, cannot be helped by the administration of male hormones even if the person was suffering from a deficiency thereof. He doesn't believe that there is such a thing as the male climacteric though there is a difference of opinion

on that subject in medical circles, [211] and there are a great many articles in which the male climacteric is discussed, but he does not share the opinion of those investigators. (p. 303-304.) He is a professional investigator, (p. 311) and eliminating the eunuchoids, castrates and women, he does not think that they have prescribed testosterone in his hospital during the last 5 years. He disagrees with statements concerning the male climacteric by Dr. Hans Lisser and Robert F. Escamilla appearing in Volume 46 of "The Urologic and Cutaneous Review," page 87, February, 1942. (p. 313-315.) He disagrees with statements of Dr. Harry Benjamin on the subject of impotence and its treatment by testosterone appearing in the "Urologic and Cutaneous Review," Volume 50, page 143, March, 1946, and with regard to the article by Dr. August A. Werner, entitled "The Male Climacteric: Additional Observations of 37 Patients," appearing in the Journal of Urology, Volume 49, page 82, June, 1943, he thinks they are absurd and he is in complete disagreement with them. (p. 315-316.)

Affiant has not summarized or narrated the testimony of any of the aforesaid Government witnesses dealing with their view that testosterone may accelerate the growth of carcinoma of the prostate, inhibit spermatogenesis, or cause partial sterility. The reason for this omission is that this affiant was not charged in said Criminal action with failure to adequately warn on his labeling that said product might produce those results thereof, as will be seen from an examination of Exhibits "A" and

“B” hereto. No warning statement on any of said labeling was included having to do with the subject of spermatogenesis or sterility. However, affiant was present at all times during the trial of said action which had been consolidated for trial with the case of United States v. El-O-Pathic Pharmacy, a corporation, Martin A. Clemens, an individual, et al., No. 20596, and was aware that defendants in said action had been charged with failure to contain on their labeling adequate warnings concerning the use of said product in [212] accelerating the growth of an incipient carcinoma of the prostate and the effect of said product upon sterility, and in order to comply in all respects with the contentions of the Government, as evidenced by its expert witnesses on those subjects, relabeled his products in the form and manner set forth in the Complaint for Injunction herein.

Defense Evidence

So far as material to the issues before the Court in this case, the defense evidence in said Criminal action was as follows:

I.

Dr. George E. Fakehany, M.D.

Is a Doctor of Medicine (p. 536) and prescribes testosterone on an average of once a day and has never encountered any adverse results from the use of it. (p. 542.)

He prescribes testosterone for males complaining

of the symptoms alleged in the Information of said Criminal action. (U. S. v. Parkinson.) He usually prescribes a month's supply and tries it for a certain period of time to see whether the person is relieved of the symptoms complained of. (p. 547.) Many are relieved and some not. That is quite a usual procedure in the practice of medicine. (p. 548.)

He does not submit such a patient to the tests referred to by the Government medical witnesses. (p. 553-554.) Those symptoms may or may not be caused by a hormone deficiency. (p. 582.)

II.

Dr. Paul E. Travis, M.D.

Is a Doctor of Medicine (p. 596) and he prescribes testosterone for a person manifesting the symptoms referred to in the Information in the Criminal action. (p. 598.) With some patients for whom he has prescribed testosterone, he found very definitely that the symptoms were relieved. (p. 598, 599, 600.) He does not know of any general practitioner who submits a patient to the [213] tests referred to by the Government witnesses, (p. 602) and has never encountered any adverse results from the administration of testosterone. (p. 604.)

III.

Dr. William A. Swim, M.D.

Is a Doctor of Medicine and has practiced internal medicine in Los Angeles since 1918. (p. 653.)

Was formerly a member of the Board of Medical Examiners of the State of California. (p. 654.)

If a person complained to him of the symptoms described in the Information, he would take a general history, make a physical examination and prescribe testosterone (p. 654), and has done so on many occasions and ever since there has been testosterone on the market. Testosterone in commercial quantities has been available for the last 10 years. On many such occasions he has found the individual's symptoms to be relieved and has never encountered any adverse results. He is familiar with what is known as the male climacteric and the symptoms of a person suffering therefrom are those symptoms referred to in the Information. He does not in his practice submit the patient to the elaborate tests mentioned by the Government witnesses. (p. 653-657.)

IV.

Allen H. Parkinson

Testified as a witness for the defense and stated:

That on June 24th, 1949 (following the date on which Government witness Dr. Elmer Belt testified on direct examination) he went to Dr. Belt's office on Wilshire Boulevard at 10:00 a.m. and asked to see one of the doctors, and was referred to a Dr. Ebert, and told him that he would like some testosterone. The doctor asked him if he had ever taken it before and he replied that he had two years ago in Salt Lake City. That a Dr. Openshaw pre-

scribed some. (p. 696-697.) He stated to said Dr. Ebert that [214] he had trouble with diminishing of the testicles and penis, and the doctor asked him if he was taking it then, and he replied "no," but that he continued taking it at frequent intervals because it had a tonic effect and made him feel better. The doctor asked him if a 50-mg. shot of testosterone propionate would be satisfactory, and he replied that it would. He was then shown to another room, and in a moment a laboratory assistant entered and took a blood sample from him. Then Dr. Belt entered the room, inserted his finger in the witness' rectum, and another technician entered and injected him with testosterone. Said Dr. Belt asked him what he wanted on his prescription—how many tablets he wanted—and the witness replied that he would like 100-mg. linguets of methyl testosterone. Dr. Belt then said "all right" and asked him to urinate in three glasses, which he did, and asked him how he took them, and he replied that he took 3 or 4 a day, and then maybe laid off 3 or 4 days, depending on how he felt, and then resumed. Dr. Belt replied "all right" and "what did the doctor in Salt Lake City charge you?" and the witness replied "\$5.00" and Dr. Belt replied "All right, pay the girl \$5.00 on your way out." (p. 699-700) and said Dr. Belt wrote out a prescription for 100-mg. linguets of methyl testosterone. (p. 700.)

In addition thereto, said witness testified that on June 30th, 1949, he called at the offices of a Dr. E. A. Gummig in Pasadena (p. 701) and received

a prescription for 100 tablets of methyl testosterone linguets. At no time during his visit to the doctor's office did the doctor lay any hands on him. (p. 701.)

At this point, your affiant alleges that said Parkinson testified as aforesaid on July 7th, 1949, and that on the following day, July 8th, 1949, the said Elmer Belt was recalled to the witness stand by the Government as a rebuttal witness, and testified with reference to the visit to him of said Parkinson that he did see Parkinson on June 24th, 1949; that when he went into the [215] room where Parkinson was, he reviewed the history which the other doctor had taken, that Parkinson told him that he had been receiving a weekly maintenance dose of 50-mg. of testosterone, and in so testifying the doctor testified from notes made in his office during the course of said examination by him and by some of his employees. (p. 825-826.) Parkinson asked for a prescription of 10-mg. tablets or linguets of testosterone to be taken 3 times daily. He does not think he stated that he had been taking that amount. He asked for the injection and said he was going to San Francisco and wanted to have a maintenance dose to take with him. When Dr. Belt entered the room where Parkinson was, he asked him if Dr. Openshaw referred him to them, and Parkinson said "yes." (p. 827.) That two years ago his testicles and penis had begun to atrophy and he became sexually impotent. That Dr. Openshaw of Salt Lake City had been treating him with a weekly maintenance dose of 50-mg. That he had

been away from Salt Lake City for three weeks and that his physician recommended that he come to them for treatment. That he was leaving for San Francisco shortly. Belt made a complete physical of Parkinson, observed his general makeup, his eyes, his pupils, his pharynx, his teeth, felt his thyroid, examined his thorax, took his blood pressure, determined his pulse rate and rhythm, felt of his abdomen, looked at his extremities, tapped his reflexes, examined external genitalia, put a finger in his rectum and examined his prostate and as a result found no contra indications for the use of testosterone. He instructed his technician to take a specimen of his blood and he had already been instructed to urinate in three glasses which he did, and that material was examined. The reason for taking the blood sample was that Parkinson said he intended to return and the doctor wanted to know whether the acid or alkaline phosphatase had changed. (p. 828-829.) Before he began his examination of Parkinson, he told him that they examined people carefully who [216] asked for testosterone or who are getting it, to be sure it isn't doing them any harm. He did not wish to undermine Doctor Openshaw's authority as the man presented himself to him as a transient under the care of another physician, and it would have been poor taste and poor policy and poor judgment as well as poor medicine to interfere with the activities of his own physician. (p. 830.)

The notes of the examination from which the doctor referred disclosed the following:

“Q. Commencing with ‘Complain,’ ‘Testosterone shots only.’

What is that (indicating) ?

A. History and physical.

Q. History and physical?

A. Wait a minute. Past history.

Q. What is this?

A. H. P., past history.

Q. Oh, H. P.

A. I guess that is history and present ailment.

Q. H. P. I.? A. History of past illness.

Q. History of past illness. It reads as follows:

Two years ago, this man's testicles and penis began to atrophy and he became sexually impotent. Dr. Openshaw of Salt Lake City has been treating him with a weekly maintenance dose of 50 milligram testosterone Neo-Hombreol. He has been away from Salt Lake City for three weeks. His physician recommended that he come here for the same shots. He will be leaving here for San Francisco shortly. Wants oral prescription for Metandren 10 milligram tablets.

On the reverse side, what is this? [217]

A. Ear, nose and throat.

Q. What is this up here (indicating) ?

A. Present illness, “P. I.,” it looks like.

Q. And something here. “P. I.” the doctor says indicates present illness. The nose, ears, eyes and throat, what is that?

A. Tonsillectomy and adenoidectomy.

Q. Tonsillectomy and adenoidectomy. And then over here, “No venereal diseases, no surg-

ery, general health excellent; two children.”
What is that (indicating) ?

A. “Daughter, age 13—and a boy aged 6 and a girl aged 4.”

Q. Boy aged 6 and girl aged 4. What is that (indicating) ?

A. “Living and well.”

(p. 832, line 4 to p. 833, line 15)

and your affiant alleges that nothing on said record of examination disclosed the results of the extended physical examination of said Parkinson which said Dr. Belt testified he had conducted.

With reference to the \$5.00 fee which Parkinson had testified he was charged by Dr. Belt, said Belt explained as follows:

“A. If this patient had not been referred to me from another doctor and if this were not a routine thing, a routine procedure, we would have charged him very much more for this entire procedure. Of course, \$5.00 wasn't the total charge here. We explained to him that the laboratory test would be \$6.50, which he said he would like to have us bill him for to this false address that he gave us. This is a purely courtesy situation here. A patient [218] comes in; he is being treated by another doctor in another city; we do our best to oblige both the doctor and the patient by carrying on the procedure that the doctor feels is indicated. I asked him what Dr. Openshaw charged him for this treatment and he said \$5.00. As a matter of fact, \$5.00 is close to the cost of 50 milligrams

of testosterone propionate. I don't know actually what the cost is to our office from the pharmacy but it is not under that. We charged him the same thing that his doctor charged him, as a matter of courtesy to that doctor, and we didn't charge him for the physical examination and for the urine analysis; nothing else except for the laboratory test." (p. 835)

V.

Hannah Shinglman

This witness testified as a defense witness that on June 27th, 1949, she called at the Beverly Hills office of the Elmer Belt Urologic Group. (p. 739, 740) That she walked into the office and asked to see Dr. Belt and was informed by the nurse that he was not there. She then asked to see another doctor and was referred to Dr. Letourneau whose name appears on the prescription pad of the Belt Urologic Group (introduced into evidence in said case) as a member of said Group. Said doctor asked her what he could do for her and she told him that she and her husband had been in this locality 6 or 8 months and previously her husband had not been feeling well for the last few years—had been nervous, jumpy and irritable and that they figured he was going through the male change. That a doctor in Chicago had given him some shots; that he had put him on tablets. She showed him an empty bottle which had been a container for testosterone linguets [219] and the doctor then gave her

a prescription for 100 metandren linguets, 25-mg., 1 daily, and her husband was not present at any time. (p. 745-746)

VI.

Hazen S. Parkinson

This witness testified for the defense as follows:

That on Sunday, June 26th, 1949, he arrived in Chicago, and on the following day called at the office of Dr. Norris J. Heckel, one of the Government witnesses heretofore referred to. (p. 753-754) In a few moments the doctor came in and the witness told Dr. Heckel that he wanted to get a bottle refilled. On the label of the bottle was the language, among others: "Metandren Linguets—500." (p. 772) He showed him a prescription that he had from Dr. Openshaw for testosterone by injection, and told the doctor that he was going on a ship and wanted to take them by mouth. (p. 773) The doctor informed him that he had just returned from Los Angeles on a trial and in reply to the question from the witness "Was there anything wrong with taking them, then, that is going to do me any danger? If there is I don't want them," the doctor replied, "Oh, no, I don't know as they will do you any damage, but we don't want them sold over the counter." The doctor took a urine sample and placed his finger up the rectum of the witness, and wrote the prescription for 500 metandren methyl testosterone linguets in the witness' presence. He told the doctor he was going on a ship and that there were 3 or 4 men to a room, and every time

you take a pill, someone else wants one, and he placed upon the prescription a dosage of 1 per day. About 5 or 6 minutes were consumed in this visit with the doctor. (p. 774-775) At the time of this visit the witness was 65 years of age. (p. 776)

Following this testimony, the Government obtained from Dr. Heckel a letter giving his version of this visit which it was stipulated between counsel would be the testimony of said doctor [220] if he were re-called. Said letter alleged that on June 24th, 1949, a Mr. Parkinson came to his office in Chicago and stated that he had been referred by a former patient; Parkinson said that he was 72 years of age, a sailor by occupation and gone from the country for long periods of time; that he was in Chicago as a transient; that his doctor in Salt Lake City had been giving him a prescription for methyl testosterone and that he had been taking this drug under his doctor's direction for the past several years; that he was leaving the country and needed about a year's supply of testosterone and requested a prescription for a year's supply. He showed Dr. Heckel a prescription for testosterone issued by another doctor. Dr. Heckel then made a physical examination of Parkinson, which included a urine analysis and a rectal examination of the prostate and found no contra indication to the use of testosterone; he found that Parkinson's prostate was of normal size, shape and consistency, with no evidence of prostatitis; and that he then renewed Parkinson's prescription for methyl testosterone linguets and advised him to report to his physician at regular intervals.

During the testimony of said Parkinson, affiant herein and defendant in said action sought to elicit from said witness testimony concerning certain general practitioners called upon at random by said Parkinson during the course of said trial, from whom in each instance he obtained prescriptions for methyl testosterone without any examination being conducted. The purpose of said testimony was to dispute the testimony of Government witnesses that general practitioners would not prescribe said drug without elaborate examinations to determine whether or not the individual was suffering from a male hormone deficiency or carcinoma of the prostate was indicated. Said offer of proof was refused but affiant herein alleges that he is now ready and able to prove all of the matters and things embraced in said offer of proof, and [221] therefore alleges that said offer of proof was and is now as follows:

“I also offer to prove that Mr. Parkinson called on several doctors, on the dates mentioned on certain prescriptions, throughout parts of Los Angeles County, and talked at random; that in each instance he went into the doctor’s office, told the doctor that he wanted this same bottle, the one he used when he saw Dr. Heckel, refilled, and asked for a prescription; that in each instance he received a prescription for these linguets and on no occasion was anything said to Mr. Parkinson about sterility or fertility or cancer of the prostate, nor did any of the doctors lay a hand on him, and he did not call on

any doctor who turned him down on the request for a prescription.

“The doctors that would be subject to Mr. Parkinson’s testimony in that regard would be Dr. G. G. Ferbryck, M.D., 516 Professional Building, 117 East 8th Street, Long Beach, California, who wrote out a prescription for Metandren Linguets, one a.m. and p.m., and the date was June 29, 1949; Dr. Wayne P. Hanson, in the same building, on June 30, 1949, wrote out a prescription for 500 10-milligram Metandren Linguets, directions, one linguet daily; that he also called on Dr. George D. Stilson and Dr. Milo Ellik, together in the same office, 511 Professional Building, 117 East 8th Street, Long Beach, on June 30th, and received a prescription from Dr. Ellik for 500 Metandren Linguets, directions, as directed; that he called on Dr. Raymond W. Kelso on June 30, 1949, the doctor’s address being 117 East 8th Street, Long Beach, who wrote out a prescription for 250 [222] 10-milligram Metandren Linguets, with directions, dissolve one on tongue each day; that he called on George B. Hanson, M.D., 716 Professional Building, 117 East 8th Street, Long Beach, on June 30, 1949, received a prescription for 250 Metandren Linguets, 10-milligrams, directions, one per day; that he called on Dr. H. F. Gramlich on June 30, 1949, address, 117 East 8th Street, Long Beach, and received a prescription for one bottle of metandren linguets, directions, as directed; that he called on Dr. P. W. Prince of the Bishop Clinic staff, 117 East 8th Street, Long Beach, on June 30, 1949, and received a prescription

for 250 10-milligram Metandren Linguets, directions, I guess it is, one daily, dissolve in mouth; that he called on Dr. L. L. Wiltse, 714 Professional Building, 117 East 8th Street, Long Beach, on June 30, 1949, and received a prescription for 500 Metandren Linguets, directions, take as directed; that he called on Dr. Marvin R. Lauer, 829 East Compton Boulevard, Compton, California, on July 2, 1949, and received a prescription for 500 Metandren Linguets, 10-milligrams, directions, use as directed; that he called on Dr. Francis J. Ort, 107 North Santa Fe Avenue, Compton, California, on July 2, 1949, and received a prescription for 500 Metandren Linguets, directions, two daily; that he called on Dr. L. C. Lowe, 706 South Hill Street, Los Angeles, on July 1, 1949, and obtained a prescription for 500 Metandren Linguets, 10-milligrams, directions, as directed; that he called on Dr. Glenn E. Jones, 403 West 8th Street, Los Angeles, on July 1, 1949, and received [223] a prescription for 500 Metandren Linguets, 10-milligrams, directions, one or two per day; that he called upon Dr. R. L. Byron, 1015 Chapman Building, 756 South Broadway, Los Angeles, on July 1, 1949, and received a prescription for 500 Metandren Linguets, 10-milligrams, directions, one as directed. (p. 764-767)

The Re-Labeling of Said Products Subsequent
to the Aforesaid Judgment of Conviction

Immediately following the judgment of conviction in said criminal action, affiant consulted with expert counsel in labeling matters and legal counsel on the subject of re-labeling said product so as to conform

to the objections made by the Government and disclosed by Government evidence in said criminal action. In so doing, affiant had in mind that said Government witnesses, with the sole exception of Dr. Charles Huggins, had testified that methyl testosterone was of great value in relieving the symptoms referred to in the Information in said criminal case provided that the individual was suffering from a male hormone deficiency; and that said symptoms might, however, be caused by conditions and diseases other than a male hormone deficiency, and that only a doctor could correctly diagnose the condition.

Your affiant was well aware of the allegations in the Information, entitled *United States of America v. El-O-Pathic Pharmacy, et al.*, No. 20596, in which Martin A. Clemens was likewise a defendant, charging that the labeling there failed to warn the user that methyl testosterone might accelerate the growth of an incipient carcinoma of the prostate and might cause sterility. Affiant alleges that in said criminal Information, so filed against *El-O-Pathic Pharmacy, et al.*, the term "carcinoma of the prostate" was employed as distinguished from "cancer of the [224] prostate." Therefore, and notwithstanding the fact that in the criminal action filed against your affiant no charge was made that the warning statements contained on his label and represented by Exhibits "A" and "B" hereto, did not constitute adequate warnings, nevertheless, for the protection of the public and to warn the user in a manner consistent in all respects to meet the objections of the Government in the criminal action against *El-O-Pathic*,

your affiant with the aid and assistance of expert counsel aforesaid, revised said warning statement in the manner and form displayed upon the labeling and set forth more fully in the Complaint herein. In all other respects the labeling formerly employed by affiant was entirely discarded and entirely re-drafted. In order to eliminate the objections of the Government that said product should not be continued over a period of time unless under the supervision of a physician, in that sterility might be caused thereby or a carcinoma of the prostate might be accelerated in growth thereby, affiant caused to be placed on said label, among other things, language to the effect that said product should be taken, 1 tablet upon arising before breakfast, or 1 tablet shortly before retiring, and that "the maintenance dosage can be extended from 3 to 6 months under the supervision of a physician. (Emphasis added.)

In order to overcome the objections made by the Government in said criminal action that an individual layman could not diagnose his need for said product, affiant caused also to be placed upon said label directions as follows:

"For use by adult males deficient in male hormone when small dosages of male hormone are prescribed or recommended by a physician, for palliative relief of such symptoms." (Emphasis added.)

As a further caution to users of said product that a physician should be consulted for the purpose of determining [225] whether or not the symptoms manifested were the result of a male hormone deficiency, and further, explanatory of the label lan-

guage above referred to that the product was to be used when "prescribed or recommended by a physician," affiant caused to be added to said label the following:

"It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted since testosterone will not aid or relieve symptoms not associated with male hormone deficiency."

During the course of the said criminal action, as part of the Government's evidence directed against the defendants El-O-Pathic Pharmacy, and Martin A. Clemens in case No. 20596, some witnesses for the Government testified that should testosterone be taken by young men who are desirous of stimulating their sexual desire and ability it might result harmfully to them unless under the guidance of a physician. Therefore, in order to meet said objections, affiant caused to be placed upon said label the following:

"Children and young adults must not use except under constant direct supervision of a physician." (Emphasis added.)

In order to meet the objections of the Government and the testimony of witnesses produced by the Government in said criminal action in the case of United States v. El-O-Pathic Pharmacy, et al., Claim No. 20596, that the labeling involved therein did not contain adequate warnings against the use of said

product when carcinoma of the prostate was indicated and without adequate warnings of the use of said product might cause sterility, affiant caused to be placed on said labeling the following cautionary [226] language, and discarded the cautionary language formerly employed by him and contained on Exhibits "A" and "B" hereto (to which no objection was made in said criminal action):

"The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate, or by anyone with cardiovascular disease, defects of spermatogenesis, sterility whether absolute or partial, or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed." (Emphasis added.)

In response to the allegations contained in the Complaint for Injunction herein, and the Affidavits filed in support thereof, that 5-milligrams of methyl testosterone has no therapeutic value, affiant alleges as follows: that the United States Pharmacopoeia lists the dosage of methyl testosterone to be:

"Average dose, sublingual, 5-milligrams"

That the American Medical Association, in the 14th Edition of "Useful Drugs, 1947" lists under methyl testosterone the following:

"Dosage: average dose, sublingual, 5-milligrams"

That the American Medical Association in its publication "Epitome of the Pharmacopoeia of the United States" and the "National Formulary, 8th Edition," list under methyl testosterone the following:

"Sublingual, 5 milligrams, Methyl testosterone usually available in tablets containing these amounts."

In addition thereto the witness Hazen S. Parkinson in the aforesaid criminal action instituted and tried against affiant [227] as aforesaid, testified that when he called upon the Government witness Dr. Norris J. Heckel he requested and obtained from said witness a prescription for 500 Methyl Testosterone Linguets, each containing 5-milligrams of methyl testosterone, and the directions upon said prescription, so written by said Government witness, Dr. Norris J. Heckel, directed said Parkinson to take one of said linguets per day.

Your affiant further alleges that in said criminal action, United States v. El-O-Pathic Pharmacy, et al., No. 20596—Criminal, there was involved in Counts XII, XIII and XIV thereof, linguets each containing 5-milligrams of methyl testosterone, but that no charge was made in said Information or otherwise during the course of said trial that said linguets contained no more than 5-milligrams of methyl testosterone had no therapeutic value.

Affiant further alleges that for approximately the 18 months preceding the institution of said criminal action against him in April, 1949, he consistently sold, offered for sale and shipped in inter-

state and intrastate commerce methyl testosterone containing no more than 5-milligrams per tablet or linguet but that no charge was made in said criminal action instituted against him, nor has any been made until the filing of this action that 5-milligrams per day of said product had no therapeutic effect. Your affiant alleges that he had shipped said product containing no more than 5-milligrams for said period of time (18 months) and that during said period your affiant had handed to inspectors of said Food and Drug Administration, who called at his place of business, samples of said 5-milligram product, and all of this long prior to the institution of said criminal action and during the time that the shipments charged in said criminal Information, *United States v. El-O-Pathic Pharmacy, et al.*, No. 20596, against him took place.

Your affiant further alleges that he is informed and [228] believes and therefore alleges that the law of the State of California does not, nor does any United States statute or rule or regulation of any administrative agency thereof require that methyl testosterone in linguet or tablet form be sold only by prescription of a physician. That notwithstanding said fact the said Food and Drug Administration of the United States Government will not approve any labeling of such product for sale without prescription regardless of the warnings contained thereon, and regardless of the fact that the labeling does, as does the labeling subject of this Complaint, repeatedly advise the user against the use of said product except upon recommendation and under the supervision of said physician.

In addition thereto your affiant alleges that an inspector of the Food and Drug Administration, working out of the Los Angeles station and whose last name is Woussatt, stated to your affiant at affiant's place of business, 1067 East Anaheim Street, Long Beach, California, that the only labeling of methyl testosterone that would meet with the approval of the Food and Drug Administration was a label which contained the statement:

“Caution: to be dispensed only by or on the prescription of a physician.”

and that regardless of the extent or content of the labeling employed and accompanying such product the Food and Drug Administration would never permit the said product to be sold over-the-counter and not on prescription.

Subsequent to said Judgment in said criminal action on July 13, 1949, affiant completely revised the labeling of said product as hereinbefore alleged and on or about September 1, 1949, affiant mailed circulars to retail druggists in California and other states throughout the United States soliciting their business for the purchase by them from affiant of said methyl testosterone so re-labeled, as aforesaid and as more fully set forth [229] in the Complaint for Injunction herein. In connection with such circularization, thousands of said circulars were mailed to retail druggists doing business solely within the state of California. Your affiant is informed and believes and therefore alleges that many, if not the majority, of said druggists doing

business in California are members of the Southern California Pharmaceutical Association, Ltd., and requested advise from said Association whether said product might be sold by them over-the-counter without a prescription.

Your affiant is further informed and believes and therefore alleges that said inquiry was prompted by reason of the fact that following the conclusion in said criminal action some articles appeared in national and local drug journals advising of the outcome of said action and stating that as a result thereof said product could not be sold except on prescription; that on receipt of said inquiries from said druggists said Southern California Pharmaceutical Association, Ltd. on or about September 15, 1949, addressed a letter to Robert S. Roe, Chief of the Los Angeles District of the Food and Drug Administration, and which letter in words and figures was as follows:

“Robert S. Roe, Chief, Los Angeles District,
Food and Drug Administration,
1401 So. Hope Street,
Los Angeles, California.

“Dear Mr. Roe:

“Enclosed herewith are advertising folders that have been distributed to Pharmacists throughout Southern California. Our members have forwarded them to us with the question, ‘Can we sell them over the counter’ without becoming subject to prosecution by the Federal Food & Drug Administration? [230]

"We are at a loss to know just what to tell them as we were under the impression Hormones had been ruled unsafe for self-medication.

"I would appreciate an opinion from your office regarding this practice.

"Respectfully,

"GEORGE O. BAIRD,

"Executive Secretary."

That within a few days after receipt of said letter said Roe addressed a reply, as follows:

"Dear Mr. Baird:

"I have your letter of August 29, transmitting copies of advertising folders that have been distributed to Pharmacists throughout Southern California. This material offers Hormones for over the counter sale and you request my comment on the application of the Federal Food, Drug and Cosmetic Act.

"It is our view that products containing significant amounts of hormones are not suitable for over the counter distribution, because adequate directions for use and adequate warnings can not be devised that will enable the safe and effective use of such products by the lay person. Consequently, such preparations should be reserved for prescription use. The over-the-counter sale of such products received in interstate commerce would constitute a violation of the Federal Act.

"It is our view that products containing Therapeutically insignificant amounts of hormones would

be worthless and labeling [231] representing them as hormone preparations or as preparations intended for use in treating hormone deficiencies would be misleading.

“Very truly yours,

“ROBERT S. ROE,

“Chief, Los Angeles District.”

Affiant alleges that thereafter said Southern California Pharmaceutical Association, Ltd., forwarded copies of said exchange of correspondence to all of its member retail druggists, and thereafter said exchange of correspondence appeared in national and local drug journals.

Your affiant is informed and believes and therefore alleges that said Food and Drug Administration has formed a policy to prevent the sale of methyl testosterone except upon prescription; regardless of the fact that there is no statute, rule or regulations preventing the sale except upon prescription; that said Food and Drug Administration intend to continue to harass, annoy and oppress your affiant by vexatious litigation in order that this policy may be carried into effect, and it is hoped that affiant find himself no longer financially able to continue; that said letter of said Robert S. Roe was calculated and intended to destroy affiant's outlets during the pendency of this litigation, notwithstanding the fact that any or all transactions had or contemplated between affiant and the druggists in the State of California would be intrastate

transactions and wholly removed from the jurisdiction of the Federal Food and Drug Administration.

Your affiant alleges that, as disclosed by said reply of Robert S. Roe, there is no intimation or suggestion that the question which is the subject of his letter is now and was at that time involved in litigation before this Court.

/s/ ALLEN H. PARKINSON.

Subscribed and sworn to before me this 3rd day of November, 1949.

[Seal] /s/ EUGENE M. ELSON,

Notary Public in and for

Said County and States.

Exhibit A

The Male Hormone

The discovery of the Male Sex Hormone is one of the achievements of modern medicine on which the public is comparatively uninformed. Yet it is truly a tremendous accomplishment.

Prof. Ruzicker, a Swiss chemist, succeeded in making Testosterone, "the most potent male hormone" by synthetic means; and for this he received The 1939 Nobel Prize in Chemistry.

"Science is unlocking the secrets of Male and Female sex hormones. Years of scientific effort and research have established that these hormones accomplish many things which up to a few years ago were thought to be impossible. These discoveries are far-reaching and assisting millions of men

and women to lead happier lives, and are helping to relieve some of the many conditions associated with middle age. [233]

Male Hormone Deficiency

The average man in his late forties begins to enter what is called the "Climacteric" period of which time the body undergoes a radical change. Although most of these changes may start during middle age, they may also show up at almost any time. As a rule there may be flushes, sweats and chills. Lack of sexual power, impaired memory, irritability, inability to concentrate on activities or a tendency to evade them, nervousness, depression, general weakness and poor physical strength are some of the major signs which are associated with this declining period.

Impotence

Lack of sexual desire and inability to perform the sexual act is one of the most common complaints of the male "climacteric." When due to deficiency of the male sex hormone, these conditions usually respond to male hormone therapy, which assists in restoring sexual desire and ability to fulfill it. In addition to helping re-establish potency, the male sex hormone helps to relieve other conditions which frequently occur during this period. [234]

Results from Male Hormone

These social, sexual, physical and mental conditions may be relieved by the use of the male sex

hormones, which sometimes bring about startling changes. At first, it may be noticed there is a marked improvement in physical and mental work and a tonic action resulting in renewed vigor. A better attitude towards business and social life is frequently observed. Nervousness, exhaustion and melancholy may disappear and in the large majority of instances the improvement may persist over a long period of time.

Many excellent Reports for the Non Professional layman have already appeared in the following publications:

Readers Digest by Paul de Kruif, July, 1944—
August, 1946.

Newsweek, March, 1943.

Time, May 28, 1945.

Newsweek, May 28, 1945.

Liberty, February 2, 1946.

Paul de Kruif's sensational book, "The Male Hormone."

Double Strength

Just One Tablet a Day

30 Day Supply.....	\$10.00
90 Day Supply.....	30.00

Regular Strength

30 Day Supply.....	\$ 5.00
90 Day Supply.....	15.00

Mailed in Plain Package

Send Check or Money Order

C.O.D.'s Accepted—Plus Postage

All Orders Sent Airmail

Same Day Received

Hudson's

Multi Vitamin Tablets

At amazing savings, Hudson leads the way in supplying the vitamin needs of millions. Our multi vitamin tablets, at a price within reach of all, now include Folic Acid, the amazing new blood-building discovery for the growth of red blood cells.

Here combined in one small capsule, you get Ten Vitamins, including the sensational new vitamin Folic Acid, which has stirred the medical world and marks the greatest advance in blood-building since the discovery of liver.

Nowhere in America will you find so reasonably priced, such unitage in a single tablet. No matter what vitamins you have used or how much you have paid for them, you should test the benefits of this new multi vitamin now.

Multi vitamins are especially recommended while taking hormones.

You Need Take Only 1 Tablet Daily

Each tablet contains:

Vitamin A (Fish Liver Oils)	5,000 I.U.	125% MDR
Vitamin D (Irrad. Ergosterol)	500 U.S.P.	125% MDR
Vitamin B ₁ (Thiamin)	3.0 Mg.	300% MDR
Vitamin B ₂ (Riboflavin)	2.0 Mg.	100% MDR
Vitamin B ₆ (Pyridoxine)	0.5 Mg.	*
Vitamin C (Ascorbic Acid)	30.0 Mg.	100% MDR
Calcium Pantothenate	5.0 Mg.	*
Niacin	10.0 Mg.	*
PABA	1.0 Mg.	*
Inositol	1.0 Mg.	*
Choline	5.0 Mg.	*
Folic Acid	0.05 Mg.	*

MDR—Minimum Daily Requirement

* —Minimum Daily Requirement Not Known

Hudson's Multi Vitamin Tablets

(100-Day Supply)\$4.95

The Female Hormone

(E Estradiol)

The use of Female sex hormones usually brings prompt relief from such symptoms as hot flashes, emotional disturbances and other manifestations associated with the menopause. A steady readjustment may be obtained from the use of hormones,

which help to overcome most menopausal conditions in women approaching or passing through this period.

Double Strength

30 Day Supply.....	\$10.00
90 Day Supply.....	30.00

Regular Strength

30 Day Supply.....	\$ 5.00
90 Day Supply.....	15.00

Mailed in Plain Package

Send Check or Money Order

C.O.D.'s Accepted—Plus Postage

All Orders Sent Airmail

Same Day Received

Relatively Safe

The Male and Female sex hormones as a rule are relatively safe to use; however, they should be used cautiously by some individuals. The Female sex hormone should not be used by women with cancer or pre-cancerous lesions of the breast or genital organs and should be used with care by women with a family history of frequent incidence of breast or genital cancer. The Male sex hormone should be carefully used by elderly men with cardiovascular disturbances and should not be used if there is any indication of cancer of the prostate. Caution: Take only as directed.

Hudson Products Co.
341 Harding St.
Long Beach 5, Calif.

Hudson Products Company
341 Harding St., Long Beach 5, Calif.

Gentlemen: Please rush my order via first class mail
today.

No. Desired	Amount
Bottles of Hudson Multi Vitamin Tablets (100 tablets)	\$4.95
	Total

I am enclosing cash.... check.... money order....
C.O.D.....

Name

Address

City..... Zone.... State.....

All Hudson products are sold on a money back if
not satisfied agreement. [235]

Exhibit B

The Story of Hormones

Hudson Products Company, Long Beach, Calif.

Index

The Story of Hormones

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How It All Began . . .

Far-reaching discoveries about male and female sex hormones are among the important achievements of modern medicine on which the general public is comparatively uninformed. Yet recent scientific research has established beyond doubt that treatment with hormones can bring about human benefits believed impossible until a few years ago.

As a result of incessant experiments with first the male and then the female hormones, science today assists millions of men and women to lead happier lives. Many conditions formerly thought to be inevitable with middle age can now be relieved.

For years certain scientists experimented with

extracts and compounds of the sex hormones without satisfying results. Then, in 1935, came the first real step toward today's tremendous accomplishments with hormones—the isolation of a crystalline potent androgen from a bull's testes by a man named Laquer and his associates in Amsterdam. Laquer called the new substance "Testosterone." Today methyl testosterone is recognized as the most potent form of the male hormone.

Following Laquer's discovery a Swiss chemist, Prof. Ruzicker, succeeded in making testosterone by synthetic means. Ruzicker's work confirmed the structure of natural testosterone and won him the 1939 Nobel Prize in Chemistry. Androgenic (male hormone) therapy was thus removed from the realm of speculation and the unbiased scientific study of the physiologic and therapeutic activity of the sex hormone began in earnest.

How Hormones Affect

Physical Development and Processes

From puberty to late middle life, and sometimes even in old age, the testes (stimulated by the anterior pituitary gland) produce appreciable amounts of the male sex hormone. Absorbed into the blood stream, which carries it to all parts of the body, the male sex hormone has a variety of functions. For convenience they may be divided into four groups:

1. Influence on male reproductive organs
2. Influence on secondary sex characteristics
3. Influence on other endocrine glands
4. Influence on other organs, tissues and metabolic processes [238]

How Hormones Affect Male Reproductive Organs

The primary function of the male sex hormone is to regulate development and growth of the male reproductive organs. Even before a child is born, male sex hormone production is stimulated by the anterior pituitary gland of the mother-to-be, thus exerting its effect on the fetus.

Proper growth during puberty of the penis, scrotum, prostate, seminal vesicles, and Cowper's gland depends upon the presence of the androgenic (male) hormone. It may also be responsible for early descent of the testes. The male reproductive organs cannot function properly even after full development without an adequate supply of the male sex hormone. Sexual desire and potency are entirely dependent upon the amount and activity of the hormone.

How Hormones Affect Secondary Sex Characteristics

An increase of the androgenic hormone during puberty promotes development of secondary sex characteristics. Accordingly, in men, facial and pubic hair appears. The masculine type of skeleton and muscles develop. Fat deposits are distributed in such a way as to form the masculine type figure. The voice deepens, and the masculine behavior pattern of aggressiveness, vigor, and self confidence also becomes evident. It is interesting to note that marked muscular development has been pro-

moted in animals and in men by the therapeutic administration of the male sex hormone.

Concerning Male Disorders

The Male Climacteric or "Change of Life"

The climacteric in women is clearly defined because of cessation of menstruation. Since men do not menstruate, it was assumed for a long time that they did not have a climacteric. The male climacteric develops gradually, progresses slowly, and may occur relatively early or late in life. Thus it often represents a complex and confusing diagnostic problem.

During this transitional period of involuntional gonadal changes, some men are subject to a variety of distressing and discouraging complaints which may seriously interfere with their capacity for work or enjoyment of leisure. Symptoms which are troublesome in one patient may be entirely absent in another, and concomitant complaints of non-hormonal origin may add to the diagnostic difficulties of a particular case.

Although manifestations of the male climacteric are most frequent in patients in their forties and fifties (the average age in women is 40.8), the possibility of hormonal imbalance must not be overlooked in younger men. Cases in the fourth and seventh decades of life are by no means uncommon. For men from 50 to 65 who complain of vague and often apparently unrelated symptoms (and who under careful study reveal signs of the climacteric) use of methyl testosterone has been urged. [239]

Symptoms of the Male Climacteric

The discomfort men suffer during the climacteric results principally from subjective rather than objective symptoms. These symptoms are classified as (1) nervous, (2) circulatory, and (3) general.

Nervous Symptoms

Practically all patients who can be considered to be suffering from this condition have a feeling of nervous tension or "intense subjective nervousness." There is "inward tremulousness" which is aggravated by fatigue or excitement. Many are nervous and irritable to the extent that they are exceptionally hard to get along with. Ordinarily small mishaps, arguments and annoyances which are normally of little importance occasion considerable nervous and mental disturbance. Many patients complain that they wake up at night and find their hands and arms, or feet and legs, numb. There may also be itching, prickling, or tingling of the skin. Headaches of the non-migrainous type often occur. The two types of headache which are most important from a diagnostic point of view are (1) those in which there is a feeling of great weight upon the head or a feeling of pressure; and (2) those in which the pain may radiate to the neck over the back of the shoulders and down the spine. The latter type headache may last from a few hours to several days, often causing the patient to complain of a mental haziness for days.

A decrease in the ability to concentrate and faulty

memory is frequently complained of, and depression or melancholia are often encountered. Intellectual changes in male climacteric patients have been described as "lack of interest in social and business life, lack of mental concentration and energy . . . a feeling of inadequacy or impotency. Occasionally the individual conceives himself to be useless, hopeless and burdensome."

Circulatory Symptoms

Hot flashes occurred in about a third of recent case studies. They are usually of short duration but are very uncomfortable and patients sometimes compare them to feelings of smothering. They may be accompanied by sweating and chilly, creepy sensations.

General Symptoms

This group of symptoms includes tiring easily, decrease in potency and libido, constipation and the tendency to gain excessive weight.

Vague digestive complaints and precordial, angina pectoris-like pains may also be outstanding symptoms. Urinary symptoms, such as frequency, nocturia, dribbling and inability to start urinary stream are invariably associated with changes in the prostate and seminal vesicles.

Treatment for Male Climacteric

The gratifying effectiveness of replacement therapy with male hormones in the male climacteric has been confirmed by a large number of observers.

Adequate hormone therapy produces in many cases "genuinely desirable results." Patients who have feared they might be mental cases because of depression and nervous instability gradually regain confidence in their mental reactions and decisions. Patients usually report that they regain their grip on life shortly after the start of treatment, and their capacity for mental and physical work is often notably increased. [240]

Impotence

As has already been mentioned, decreased sexual desire or complete impotence may accompany the male climacteric, though it may occur also at other times. Indeed, adequate sexual competence depends upon the integrated co-operation of several factors. Anatomic, hormonal, neurologic, psychologic, and emotional components are involved in the attainment of full potency. Impotence may be caused by a disturbance of one or several of these factors.

When impotence is caused by male sex hormone deficiency, replacement therapy with methyl testosterone is indicated. In most cases this will restore sexual desire, potency and genital tract tone with adequate sexual competence. At the same time there is often an improvement in physical and mental mal-conditions. Methyl testosterone is especially beneficial in young and middle aged men with diminished potency, who were formerly normal.

The Female Hormone

Women, too, can find extraordinary benefits in the therapeutic administration of the sex hormone. Prompt relief is obtainable from such unpleasant menopause disturbances as hot flashes, emotional upsets and other "change of life" manifestations. A steady readjustment may occur through the use of the natural hormone, which helps overcome most menopausal conditions in women approaching or passing through this period.

Hormonal Treatment for Breast Development

Small or undeveloped breasts are frequently a cause of worry to some women. In the form of a specially prepared and medically approved ointment, the female sex hormone used for therapy produces a direct action on the mammary gland. Applied directly to the breast, this hormonal ointment stimulates growth considerably, yet helps retain the pointed shape of the young breast. The desired stimulation results from a re-vitalized concentration of the sex hormone in the body tissue. Marked results are obtainable after 60 to 90 days use.

25 Day Supply of Ointment

(125,000 International Units) \$12.95

2½ Month Supply of Ointment

(375,000 International Units) \$33.95

Warning:

Although both male and female sex hormones are relatively safe to use as a rule, scientific tests prove that they should not be used by anyone suffering from cancer. Neither should they be used by persons suffering from serious heart trouble. Also, hormone therapy should be used with caution by senile men in whom excessive stimulation of waning sex power may be physiologically undesirable. [241]

New Low Prices

The Male Hormone

30 day supply.....	10.00
90 day supply.....	30.00

The Female Hormone

30 day supply.....	\$ 5.00
90 day supply.....	15.00

Mailed in plain package Air Mail same day order received. Send cash, check or money order.

C.O.D. you pay postage.

Hudson Products Co.

341 Harding St.

Long Beach 5, Calif.

Rceipt of copy acknowledged.

[Endorsed]: Filed November 3, 1949. [242]

[Title of District Court and Cause, No. 10391-PH.]

AMENDMENT TO THE ANSWER

As a Separate Affirmative Defense Defendants
Allege:

I.

That for some time last past and now the Food and Drug Administration of the Federal Security Agency of the United States Government has interpreted, applied and enforced and does now interpret, apply and enforce Section 502(f)(1) of the Federal Food, Drug and Cosmetic Act in an arbitrary, capricious and unlawful manner, wherein and whereby defendants herein are deprived of their property and liberty without due process of law in violation of Article V of the Amendments to the Constitution of the United States in the following particulars:

That officers, agents and representatives and employees [246] of said Food and Drug Administration of the United States Government have uniformly enforced, applied and interpreted Section 502(f)(1) of said Food, Drug and Cosmetic Act to mean that the term "adequate directions for use" as used in said Section enables and empowers them to decide and determine whether a particular drug and particularly methyl testosterone sold by defendants should or should not be sold over the counter to lay-persons regardless of the statements and contents of the labeling thereon; that should

said officers of said Administration determine and decide that a particular drug and particularly methyl testosterone sold by the defendants should not be sold except on the prescription of a physician, no directions for use for sale of said product over the counter to lay-persons can be adequate and that the only manner in which, under such circumstances, the requirement that "adequate directions for use" be provided on the labeling is to provide thereon that said product should be sold only by or on the prescription of a physician. Notwithstanding the fact that there exists no act of Congress or rule or regulation by any Federal administrative body or tribunal prohibiting the sale of said product except on prescription.

By reason of said arbitrary, capricious and invalid interpretation of said statute applied and enforced by said Administration and the officers, agents and employees thereof defendants are not nor are any of them enabled to know whether at any time any drug product sold by them is or is not in the opinion of said Food and Drug Administration a product which may be sold over the counter to lay-persons regardless of the statements and contents of the labeling thereon or should be sold only on the prescription of a physician.

By reason of said interpretation, application and enforcement of said statute defendants herein are subjected to possible prosecution under said Federal Food, Drug and Cosmetic [247] Act at each time a shipment of a drug product is made in inter-

state commerce, depending entirely upon the whim, opinion, decision or belief of said Food and Drug Administration rather than upon the provisions of said Section 502(f)(1) of the Federal Food, Drug and Cosmetic Act.

By reason of said interpretation, application, and enforcement of said statute as against these defendants they are deprived of their liberty and property without due process of law in violation of Article V of the Amendments to the Constitution of the United States.

II.

Defendants further allege that should said Section 502(f)(1) of the Federal Food, Drug and Cosmetic Act, properly interpreted, empower said Food and Drug Administration to apply and enforce said Section as hereinbefore alleged, then said Section 502(f)(1) of the Federal Food, Drug and Cosmetic Act constitutes an invalid delegation of legislative authority to an administrative body, to wit: The Food and Drug Administration of the Federal Security Agency of the United States.

HOWLETT and ELSON,

By /s/ EUGENE M. ELSON,

Attorneys for Defendants.

Duly verified.

[Endorsed]: Filed November 10, 1949. [248]

[Title of District Court and Cause No. 10391-PH]

STIPULATION

It Is Hereby Stipulated between counsel for the respective parties, as follows:

I.

That there is on file with the Clerk of the above-entitled Court in United States of America vs. El-O-Pathic Pharmacy, et al., Civil Action No. 10266-PH, among other things, "Points and Authorities in Opposition to Order to Show Cause re Preliminary Injunction"; "Supplemental Points and Authorities in Opposition to Order to Show Cause re Preliminary Injunction"; "Supplemental Affidavit of Martin A. Clemens" (having to do with the allegation in the Complaint for Injunction that 5-milligrams per day of methyl testosterone do not have any therapeutic value); "Supplemental [250] Affidavit of Martin A. Clemens," dated October 21, 1949 (attaching labeling used in connection with certain patent medicines described therein); and "Affidavit of Eugene M. Elson." That the aforesaid documents were filed by the defendants in said action in opposition to the order to show cause issued therein why preliminary injunction should not issue as prayed for.

II.

That the aforesaid affidavits, and each of them, alleged matters and things which are claimed by the defendants to be pertinent to the response of the

defendants in the above-entitled action to the order to show cause issued therein why a preliminary injunction should not issue, and that said affidavits, and each of them, so filed in said action, entitled United States of America vs. El-O-Pathic Pharmacy, a corporation, et al., Civil Action No. 10266-PH, may be considered by the Court and counsel with the same force and effect as though the same had been filed herein by the defendants herein in opposition to the order to show cause issued herein.

III.

That said "Points and Authorities in Opposition to Order to Show Cause re Preliminary Injunction"; and "Supplemental Points and Authorities in Opposition to Order to Show Cause re Preliminary Injunction" so filed in said action entitled United States of America vs. El-O-Pathic Pharmacy, et al., No. 10266-PH, may be considered by the Court and counsel with the same force and effect as though the same had been filed herein in response to the order to show cause why preliminary injunction should not issue herein, provided, however, that counsel for defendants herein may file on behalf of the defendants in this action points and authorities in opposition to said order to show cause, indicating any additional points and authorities applicable to this action alone, and indicating therein any portion of the aforesaid points and authorities and supple-

mental points and authorities which are not [251]
applicable to this action.

Dated: November 10, 1949.

HOWLETT and ELSON,

/s/ EUGENE M. ELSON,

Attorneys for Defendants.

JAMES M. CARTER,

United States Attorney,

CLYDE C. DOWNING,

Assistant United States Attorney, Chief Civil Di-
vision,

/s/ TOBIAS G. KLINGER,

Assistant United States Attorney, Attorneys for
United States of America.

It Is So Ordered this 10th day of November, 1949.

/s/ HARRY C. WESTOVER,

United States District Judge.

Receipt of Copy acknowledged.

[Endorsed]: Filed November 10, 1949. [252]

In the United States District Court for the Southern District of California, Central Division

Civil No. 10391-HW

UNITED STATES OF AMERICA,

Plaintiff,

vs.

HUDSON PRODUCTS COMPANY, a Corporation, and its Subsidiary Firm Doing Business Under the Fictitious Name and Style, MAYWOOD PHARMACAL COMPANY, and ALLEN H. PARKINSON, an Individual,
Defendants.

FINDINGS OF FACT AND CONCLUSIONS OF
LAW ON PRAYER FOR PRELIMINARY
INJUNCTION

This Court, having considered the pleadings, affidavits, briefs, and oral arguments relating to the plaintiff's prayer for a Preliminary Injunction in this cause, and having denied said prayer on January 11, 1950, now makes the following Findings of Fact and Conclusions of Law, but expressly refrains from making any determination with respect to the ultimate issues of fact and law:

Findings of Fact

(1) If the defendants are violating the Federal Food, Drug, and Cosmetic Act, the public interest can be substantially protected by an early trial on the plaintiff's prayer for a Permanent Injunction.

(2) This case was set for trial in this Court on January 24, 1950, [254] on the plaintiff's prayer for a Permanent Injunction, and on stipulation of the parties the trial date was continued until January 31, 1950.

Conclusions of Law

(1) Where the United States seeks a Preliminary Injunction to prevent alleged violations of the Federal Food, Drug, and Cosmetic Act, and it appears that an early trial can be had on the prayer for a Permanent Injunction which will substantially protect the public interest involved, a Preliminary Injunction should not issue.

(2) The plaintiff's prayer for a Preliminary Injunction is denied.

Dated: Jan. 30th, 1950.

/s/ HARRY C. WESTOVER,

United States District Judge.

Judgment entered Jan. 30, 1950.

Receipt of Copy acknowledged.

[Endorsed]: Filed January 30, 1950. [255]

[Title of District Court and Cause No. 10391-HW Civil.]

STIPULATION AS TO RECORD

In order that this case may be disposed of as quickly as possible,

It Is Stipulated by the parties hereto, through their respective counsel, that the complete record of this case shall consist of the following documents,

all of which are filed in Civil No. 10391-HW, unless otherwise stated:

(1) The Complaint for Injunction filed by the plaintiff;

(2) The supporting affidavits filed by the plaintiff together with their exhibits—namely, the affidavits of Mr. Robert S. Roe, Dr. Clinton Hobart Thienes, Dr. Elmer Belt, and Dr. Ian Macdonald;

(3) Judge McCormick's Order To Show Cause, dated September 29, 1949;

(4) Stipulation, Consent, and Order, signed by Judge Peirson M. Hall, dated October 20, 1949, continuing hearing on Order to Show Cause;

(5) Answer and Amendment to the answer filed by the defendants; [256]

(6) Stipulation Permitting Filing of Amendment to Answer, dated November 10, 1949;

(7) The two Supplemental Affidavits of Martin A. Clemens filed in Civil No. 10266-HW;

(8) Affidavit of Eugene M. Elson filed in Civil No. 10266-HW;

(9) Stipulation dated November 10, 1949, that certain affidavits and briefs filed in Civil No. 10266 may be considered by the Court in the instant case;

(10) Affidavit of Allen H. Parkinson;

(11) Findings of Fact and Conclusions of Law of Judge Westover denying plaintiff's prayer for a Preliminary Injunction;

(12) Supplemental affidavit of Robert S. Roe filed in Civil No. 10266, subject to any objections as to relevancy and materiality;

(13) Affidavit of Walter F. McRae filed in Civil No. 10266, except paragraph (3) thereof and except Exhibit A attached to said affidavit, subject to any objections as to relevancy and materiality;

(14) The Information filed by the Government in United States v. Allen H. Parkinson, No. 20642-Criminal (S.D. Calif.);

(15) The complete transcript of proceedings, including exhibits in the case of United States v. El-O-Pathic Pharmacy et al., No. 20596-Criminal, (S.D. Calif.), which was tried together with the case described in paragraph (14) of this Stipulation, shall be considered part of the record of this case subject to any objections as to its relevancy and materiality; provided, that it is expressly understood (a) that none of the evidence in said transcript pertaining to the danger of using testosterone under certain circumstances was introduced as against said Parkinson, defendant in No. 20642-Criminal, and (b) that there was no charge made by the Government in No. 20642-Criminal that the warning statement on the labeling which related to the testosterone products there involved was not adequate;

(16) Stipulation and Order filed January 17, 1950, continuing the trial in this cause for one week; [257]

(17) If Mr. Hazen Parkinson were called to testify in this proceeding, he would testify, if permitted, in accordance with the offer of proof set forth on pages 762-767 of the transcript of record described in paragraph (15) of this Stipulation.

ERNEST A. TOLIN,

United States Attorney,

CLYDE C. DOWNING,

Assistant U. S. Attorney,

Chief of Civil Division,

/s/ TOBIAS G. KLINGER,

Assistant U. S. Attorney,

Attorneys for Plaintiff.

HOWLETT and ELSON,

By /s/ EUGENE M. ELSON,

Attorney for Defendants.

[Endorsed]: Filed January 31, 1950. [258]

[Title of District Court and Cause No. 10391-HW.]

STIPULATION AS TO RECORD

It is hereby stipulated between counsel for the respective parties in the above-entitled action as follows:

1. The answer of Hudson Products Company, a corporation; Hudson Products Company, a corporation doing business as Maywood Pharmacal Company; and Allen H. Parkinson, an individual, here-

tofore filed in the above-entitled action, in paragraph IV thereof, inadvertently described Exhibit "C" attached to said Answer and constituting page 10 of said Answer as the carton label used by Hudson Products Company, a corporation, prior to August 26, 1949. Said designation was in error and in fact said carton label designated Exhibit "C" as aforesaid is the carton label used by Hudson Products Company, a corporation, doing [262] business as Maywood Pharmacal Company since August 26, 1949.

2. Said paragraph IV of said Answer incorrectly referred to Exhibit "D" thereto and constituting page 11 of said Answer as the bottle label used by Hudson Products Company, a corporation, prior to August 26, 1949. Said designation was in error and in fact said bottle label Exhibit "D" was used by said Hudson Products Company, a corporation, since August 26, 1949.

3. Said paragraph IV of said Answer incorrectly referred to Exhibit "E" to said Answer, and constituting page 12 of said Answer, as the carton label used by said Hudson Products Company, a corporation, doing business under the fictitious firm name of Maywood Pharmacal Company, since August 26, 1949. Said carton label was in fact used by Hudson Products Company, a corporation, as such, and not

doing business under the fictitious firm name of Maywood Pharmacal Company prior to August 26, 1949.

Dated this 14th day of April, 1950.

ERNEST A. TOLIN,
United States Attorney.

CLYDE C. DOWNING,
Assistant U. S. Attorney,
Chief of Civil Division.

/s/ GEORGE E. DANIELSON,
Assistant U. S. Attorney,
Attorneys for Plaintiff.

/s/ EUGENE M. ELSON,
Attorney for Defendants.

[Endorsed]: Filed April 14, 1950. [263]

[Title of District Court and Cause No. 10391-HW]

FINDINGS OF FACT AND
CONCLUSIONS OF LAW

Plaintiff having filed a Complaint praying for a preliminary injunction and for a permanent injunction; and the defendants having appeared and answered; and the Court having denied the prayer for a preliminary injunction; and the cause having come on for trial on the plaintiff's prayer for a permanent injunction; and this cause having been consolidated for trial with U. S. v. El-O-Pathic Pharmacy, et al., No. 10-266-HW Civil; and the

parties having offered documentary evidence by stipulation; the Court now makes the following Findings of Fact and Conclusions of Law as required by Rule 52(a) of the Federal Rules of Civil Procedure:

Findings of Fact

(1) Defendant Hudson Products Company is a corporation having its principal place of business at 1067 East Anaheim Street, Long Beach, California. [264]

(2) Said Hudson Products Company also trades under the fictitious name and style of Maywood Pharmacal Company at 6812 Hollywood Boulevard, Hollywood, California. All mail orders received by the defendant Maywood Pharmacal Company are filled and mailed by the defendant Hudson Products Company.

(3) Defendant Allen H. Parkinson resides in the County of Los Angeles, California, within the jurisdiction of this Court. He is the president of said Hudson Products Company and is primarily responsible for its policies and activities.

(4) Defendant Parkinson trading as Hudson Products Company was convicted in this Court on July 13, 1949, in Docket No. 20642-Criminal, of violating the Federal Food, Drug, and Cosmetic Act by reason of their distribution of misbranded male and female hormone drugs.

(5) There is no evidence that said defendants

have continued the distribution of female hormone drugs since July 13, 1949.

(6) Subsequent to July 13, 1949, said defendants have changed the labeling of the male hormone drugs which they distribute. They will probably continue the interstate distribution of said drugs as presently labeled on a large scale unless restrained from so doing by this Court.

(7) The male hormone drugs which defendants ship interstate on mail order consist of:

(a) Methyl Testosterone linguets (5 milligrams)

(b) Methyl testosterone combined with a small amount of Vitamin B1 in linguet form (5 milligrams)

These drugs are sold in quantities ranging from 30 tablets to 180 tablets per package.

(8) Said defendants do not require a physician's prescription in their sale of said drugs.

(9) The labels which defendants use on said drugs are those which are set forth in paragraphs 6 and 7 of the Complaint, and which also comprise Exhibits C and D of the Answer filed by the defendants.

(10) The labeling of each of the male hormone drugs which said defendants distribute uses the word "physician" four times in such phrases as "under supervision of a physician." Said labeling includes a statement that a physician should be consulted before taking testosterone.

(11) The labeling of each of said drugs contains adequate directions for use.

(12) The labeling of each of said drugs contains adequate warnings.

(13) The plaintiff has not sustained its burden of proof with respect to its allegations in issue.

(14) The plaintiff has not established that a 5 milligram linguet of methyl testosterone taken once daily is ineffective in the treatment of male hormone deficiency.

Conclusions of Law

(1) This Court has jurisdiction over the subject matter of this cause and the parties thereto.

(2) The male hormone drugs distributed by defendants Allen H. Parkinson and Hudson Products Company are not misbranded within the meaning of 21 U.S.C. 352(f) (1) since the suggestion in the labeling of said drugs that they be taken in consultation with a physician constitutes adequate directions for use.

(3) The male hormone drugs distributed by said defendants are not misbranded within the meaning of 21 U.S.C. 352(f) (2) since the suggestion in the labeling of said drugs that they be taken in consultation with a physician constitutes adequate warnings against use in those pathological conditions where their use may be dangerous to health.

(4) The male hormone drugs distributed by said defendants are not misbranded within the meaning

of 21 U.S.C. 352(a) since it has not been established that the daily intake of methyl testosterone in linguet form is ineffective in the treatment of male hormone deficiency.

(5) The plaintiff's prayer for a permanent injunction is denied.

Dated: May 22nd, 1950.

/s/ HARRY C. WESTOVER,
United States District Judge.

Affidavit of service by mail attached.

[Endorsed]: Filed May 22, 1950. [266]

In the United States District Court in and for the
Southern District of California, Central Division

No. 10,391-HW Civil

UNITED STATES OF AMERICA,

Plaintiff,

vs.

HUDSON PRODUCTS COMPANY, et al.,

Defendants.

JUDGMENT

Plaintiff having filed a Complaint praying for a preliminary injunction and for a permanent injunction; and the defendants having appeared and

answered; and the Court having denied the prayer for a preliminary injunction; and the cause having come on for trial on the plaintiff's prayer for a permanent injunction; and this cause having been consolidated for trial with United States v. El-Opthic Pharmacy, et al., No. 10,266-HW Civil; and the parties having offered documentary evidence by stipulation; the Court having filed Findings of Fact and Conclusions of Law as required by Rule 52(a) of the Federal Rules of Civil Procedure;

It is Therefore Ordered, Adjudged, and Decreed that the plaintiff's prayer for a permanent injunction be, and is hereby denied, and that the Complaint for Injunction be, and is hereby, dismissed.

Dated: May 22nd, 1950.

/s/ HARRY C. WESTOVER,
U. S. District Court Judge.

Judgment entered May 22nd, 1950.

[Endorsed]: Filed May 22, 1950. [268]

[Title of District Court and Cause No. 10266-HW]
and

[Title of District Court and Cause No. 10391-HW]

NOTICE OF APPEAL

Notice Is Hereby Given that the United States of America, plaintiff above named, hereby appeals

to the United States Court of Appeals for the Ninth Circuit from the final judgment entered in the above actions on May 22, 1950.

Dated: July 17, 1950.

ERNEST A. TOLIN,
United States Attorney.

CLYDE C. DOWNING,
Assistant U. S. Attorney,
Chief, Civil Division.

/s/ GEORGE E. DANIELSON,
Assistant United States Attorney, Attorneys for
United States of America, Plaintiff.

Affidavit of Service by Mail attached.

[Endorsed]: Filed July 19, 1950. [412]

[Title of District Court and Cause No. 10266-HW]
and

[Title of District Court and Cause No. 10391-HW]

STATEMENT OF POINTS ON WHICH AP-
PELLANT INTENDS TO RELY ON THE
. APPEAL

Appellant hereby states the points upon which it intends to rely on appeal: [415]

(1) The District Court erred in holding that the labeling of appellees' drugs bears adequate direc-

tions for use, within the meaning of 21 U.S.C. 352(f)(1).

(2) The District Court erred in holding that the labeling of appellees' drugs bears adequate warnings, within the meaning of 21 U.S.C. 352(f)(2), against use in those pathological conditions where their use may be dangerous to health.

(3) The District Court erred in holding that appellees' drugs are not dangerous to health, within the meaning of 21 U.S.C. 352(j), when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling.

(4) The District Court erred in holding that the labeling of appellees' drugs [the 5-milligram methyl testosterone linguets, and the combination methyl testosterone and Vitamin B-1 linguets] is not false or misleading within the meaning of 21 U.S.C. 352(a).

(5) The District Court erred in holding that appellant failed to establish that the daily intake of 5 milligrams of methyl testosterone in linguet form is ineffective in the treatment of male hormone deficiency.

(6) The District Court erred in holding that appellees' drugs are not misbranded within the meaning of 21 U.S.C. 352(a), (f)(1), (f)(2), and (j).

(7) The District Court erred in holding that appellant failed to sustain its burden of proof.

(8) The District Court erred in refusing to issue permanent injunctions as prayed to restrain the appellees from further violations of the Federal Food, Drug, and Cosmetic Act.

Respectfully submitted,

ERNEST A. TOLIN,
United States Aatorney.

CLYDE C. DOWNING,
Assistant U. S. Attorney,
Chief of Civil Division.

/s/ GEORGE E. DANIELSON,
Assistant U. S. Attorney.

[Endorsed]: Filed July 19, 1950. [416]

[Title of District Court and Cause. No. 20596]

INFORMATION

(21 U.S.C. 331 and 333 and 352—Introduction into interstate commerce of misbranded drugs)

Count I

[21 U.S.C. 331(a), 333(a), 352(a), 352(f)(2) and 352(j)]

The United States Attorney charges:

That Martin A. Clemens, an individual, trading and doing business under the firm name M. A. Clemens Pharmacy at Los Angeles, State of California, did, within the Central Division of the

Southern District of California, on or about November 1, 1947, in violation of the Federal Food, Drug, and Cosmetic Act, unlawfully cause to be introduced and delivered for introduction into interstate commerce at Los Angeles, State of California, for delivery to Phoenix, State of Arizona, consigned to John R. Winch, a box containing a number of tablets of a drug;

That displayed upon said box was the following labeling:

Male Hormone

Each tablet contains 25 mg. testosterone the form of the true male sex hormone which is most highly effective for administration by mouth. The availability of methyl testosterone [269] makes possible the convenience of oral administration in applying androgenic therapy. The oral dose of methyl testosterone is about 1-2 tablets daily.

Trial Size	\$ 2.00
Box 30 Tablets.....	10.00
Box 60 Tablets.....	19.00
Box 100 Tablets Professional Size..	29.95

Send Mail Orders to M. A. Clemens (Pharmacist)

426 So. Spring St. Room 502-503 MAdison 6-4171

Los Angeles 13, Calif.

That accompanying said drug, was certain additional labeling relating to said drug, namely, a circular entitled "Male and Female Sex Hormones";

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid labeling of said drug contained statements which represented and suggested that said drug would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development and depth of voice; that said drug would correct lack of sexual power and impotence; that said drug would relieve and postpone the many conditions associated with middle age and would improve the sense of well being; that said drug constituted an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; that the use of said drug would result in improved physical and mental work and would exert a tonic action resulting in renewed vigor; and that said drug would impart a better attitude toward social life and would cause nervousness, exhaustion and melancholy to disappear in the average man in his late forties, which said statements were false and misleading in that said drug in the average man in his late forties, would not stimulate [270] growth and development of the sex organs and of the male sex characteristics, such as distribution of hair, muscular development and depth of voice; said drug would not correct lack of sexual power

and impotence; said drug would not relieve and postpone the many conditions associated with middle age and would not improve the sense of well being; said drug would not constitute an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; the use of said drug would not result in improved physical and mental work and would not exert a tonic action resulting in renewed vigor; and said drug would not impart a better attitude towards social life and would not cause nervousness, exhaustion and melancholy to disappear;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 352(f) (2), in that the labeling of said drug failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health in such manner and form as are necessary for the protection of users, in that each tablet of said drug contained 25 milligrams of male hormone (methyl testosterone) and the labeling of said drug failed to warn that its use may result in sterility and its use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the

meaning of 21 U.S.C. 352(j), in that said drug was dangerous to health when used in the dosage and with the frequency prescribed, recommended and suggested in its labeling, since each tablet of said drug contained 25 milligrams of male hormone (methyl testosterone) and the use of a drug containing 25 milligrams of male hormone in each tablet with the frequency prescribed, recommended and [271] suggested in the labeling, to wit, as directed on the box label, "1-2 tablets daily" and as directed in the aforesaid circular, "One tablet a day," would be dangerous to health since such use of said drug may result in sterility, and such use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth. [272]

Count II.

[21 U.S.C. 331(a), 333(a), 352(a), 252(f)(2) and 352(j)]

The United States Attorney further charges:

That El-O-Pathic Pharmacy, Inc., a corporation, organized and existing under the laws of the State of California, and trading and doing business at Los Angeles, State of California, and Martin A. Clemens, an individual, at the time hereinafter mentioned, manager and director of said corporation, did, within the Central Division of the Southern District of California on or about October 30, 1947, in violation of the Federal Food, Drug, and Cosmetic Act, unlawfully cause to be introduced and delivered for introduction into interstate com-

merce at Los Angeles, State of California, for delivery to Phoenix, State of Arizona, consigned to John R. Winch, a box containing a number of tablets of a drug;

That displayed upon said box was the following labeling:

Male Hormone

Each tablet contains 25 mg. testosterone the form of the true male sex hormone which is most highly effective for administration by mouth. The availability of methyl testosterone makes possible the convenience of oral administration in applying androgenic therapy. The oral dose of methyl testosterone is about 1-2 tablets daily.

Trial Size	\$ 2.00
Box 30 Tablets.....	10.00
Box 60 Tablets.....	19.00
Box 100 Tablets Professional Size..	29.95

Send Mail Orders to El-O-Pathic Pharmacy
11091½ No. Western Ave. Hollywood 27, Calif.

Hollywood 1722

Note: Please understand this trial size is simply an introductory package and for marked results treatment must be continued over a [273] 30-day period.

That accompanying said drug was certain additional labeling relating to said drug, namely, a circular entitled, "Male and Female Sex Hormones";

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid labeling of said drug contained statements which represented and suggested that said drug would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development and depth of voice; that said drug would correct lack of sexual power and impotence; that said drug would relieve and postpone the many conditions associated with middle age and would improve the sense of well being; that said drug constituted an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; that the use of said drug would result in improved physical and mental work and would exert a tonic action resulting in renewed vigor; and that said drug would impart a better attitude towards social life and would cause nervousness, exhaustion and melancholy to disappear in the average man in his late forties, which said statements were false and misleading in that said drug in the average man in his late forties would not stimulate growth and development of the sex organs and of the male sex characteristics, such as distribution of hair, muscular development and depth of voice; said drug would not correct lack of sexual power and impotence; said drug would not relieve and postpone the many

conditions associated with middle age and would not improve the sense of well being; said drug would not constitute an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; the use of said drug [274] would not result in improved physical and mental work and would not exert a tonic action resulting in renewed vigor; and said drug would not impart a better attitude towards social life and would not cause nervousness, exhaustion and melancholy to disappear;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 352(f)(2), in that the labeling of said drug failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health in such manner and form as are necessary for the protection of users, in that each tablet of said drug contained 25 milligrams of male hormone (methyl testosterone) and the labeling of said drug failed to warn that its use may result in sterility and its use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 352(j), in that said drug was

dangerous to health when used in the dosage and with the frequency prescribed, recommended and suggested in its labeling, since each tablet of said drug contained 25 milligrams of male hormone (methyl testosterone) and the use of a drug containing 25 milligrams of male hormone in each tablet with the frequency prescribed, recommended and suggested in the labeling, to wit, as directed on the box label, "1-2 tablets daily" and as directed in the aforesaid circular, "One tablet a day," would be dangerous to health since such use of said drug may result in sterility, and such use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth.

Count III.

[21 U.S.C. 331(a), 333(a) and 352(a)]

The United States Attorney further charges:

That El-O-Pathic Pharmacy, Inc., a corporation, organized and existing under the laws of the State of California, and trading and doing business at Los Angeles, State of California, and Martin A. Clemens, an individual, at the time hereinafter mentioned, manager and director of said corporation, did, within the Central Division of the Southern District of California, on or about December 28, 1947, in violation of the Federal Food, Drug, and Cosmetic Act, unlawfully cause to be introduced and delivered for introduction into interstate commerce at Los Angeles, State of California, for delivery to

Phoenix, State of Arizona, consigned to John R. Winch, a box containing a number of dosules of a drug;

That displayed upon said box was the following labeling:

Menformon Dosules*

Reg. U. S. Pat. Off.

“Roche-Organon”

(Female Sex Hormone Ointment in Individual
Dose Containers for Accuracy of Dosage)

Each Dosule contains 1 gram of ointment. The active ingredient of Menformon Dosules is Non-Crystalline Estrone in natural combination with insignificant quantities of Other Naturally Occurring Female Sex Hormones (equilin and equilenin) derived from pregnant mare's urine. The content of estrogenic substances present in each dosule represents the estrus producing activity of 2000 International Units of 0.2 mg. of standard crystalline ketohydroxyestratriene (estrone).

For External Use Only

*The term “Dosules” is a trade mark designating individual dose containers supplied by the owner of the trade mark.

Roche-Organon, Inc.

Nutley, New Jersey [276]

For Application:

1. Puncture the tip of the Dosule tube with pin or other pointed instrument.

2. Squeeze out all the ointment spreading it over a wide area for quick absorption.

3. Now rub in briskly for several minutes (usually five or more) until all the ointment is well rubbed in.

Caution: To be dispensed only by or on the prescription of a physician. Prescribed dose should not be exceeded.

Note: A leaflet giving dose schedules and therapeutic indications has been prepared for the convenience of physicians. For safe use, physicians are urged to obtain a copy in the event they are not familiar with the preparation.

24702

Keep in a Cool Place

That accompanying said drug was certain additional labeling relating to said drug, namely, a circular entitled, "Male and Female Sex Hormones";

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid labeling of said drug contained statements which represented and suggested that said drug would be efficacious to develop the female breasts, to stimulate mammary growth and result in definite breast growth of considerable degree, and that said drug would be efficacious in the treatment of under-developed breasts which statements in said circular were false and misleading in that said drug would not be efficacious for such purposes. [277]

Count IV.

[21 U.S.C. 331(k), 333(a), 352(a) and 352(j)]

The United States Attorney further charges:

That Roche-Organon, Inc., trading and doing business at Nutley, State of New Jersey, did, on or about August 6, 1947, ship in interstate commerce from Nutley, State of New Jersey, to Los Angeles, State of California, consigned to the Mote Company, a bottle containing a number of tablets of a drug, to wit, methyl testosterone;

That thereafter, to wit, on or about August 27, 1947, the said Mote Company did sell and deliver to M. A. Clemens Pharmacy at Los Angeles, State of California, said bottle containing said tablets of drug;

That thereafter, to wit, on or about November 18, 1947, and while said tablets of drug contained in said bottle were being held for sale after shipment in interstate commerce at the said M. A. Clemens Pharmacy at Los Angeles, State of California, Martin A. Clemens, an individual, trading and doing business as M. A. Clemens Pharmacy at Los Angeles, State of California, the defendant herein, did at Los Angeles, State of California, within the Central Division of the Southern District of California, cause to be removed a quantity of said drug, namely, 5 tablets, from said bottle and did cause to be repacked said 5 tablets of said drug so removed into an envelope and did cause to be sold and disposed of said envelope containing said tablets of said drug to one Robert C. Brandenburg solely

upon the surrender by said Robert C. Brandenburg of money in payment therefor;

That displayed upon said tablets when repacked as aforesaid, was the following labeling:

Male Hormone

Each tablet contains 25 mg. testosterone the form of the true male sex hormone which is most highly effective for administration by mouth. The availability of methyl testosterone makes possible the convenience of oral administration in [278] applying androgenic therapy. The oral dose of methyl testosterone is about 1-2 tablets daily.

Trial Size	\$ 2.00
Box 30 Tablets.....	10.00
Box 60 Tablets.....	19.00
Box 100 Tablets Professional Size	29.95

Send Mail Orders to M. A. Clemens (Pharmacist)
426 So. Spring St., Room 502-503 MAdison 6-4171

Los Angeles 13, Calif.

That on or about November 18, 1947, and while said tablets of drug were held for sale after shipment in interstate commerce as aforesaid, the said Martin A. Clemens, did at Los Angeles, State of California, cause certain additional labeling relating to said drug, namely, a circular entitled "Male and Female Sex Hormones," to accompany said tablets of drug;

That said act of causing the aforementioned circular to accompany said tablets of drug as afore-

said resulted in said tablets of drug in said envelope being misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid labeling of said drug contained statements which represented and suggested that said drug would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development and depth of voice; that said drug would correct lack of sexual power and impotence; that said drug would relieve and postpone the many conditions associated with middle age and would improve the sense of well being; that said drug constituted an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; that the use of said drug would result in improved physical and mental work and would exert a tonic action resulting in renewed vigor; and that said drug would impart a better attitude towards social life and would cause nervousness, exhaustion and melancholy to [279] disappear in the average man in his late forties, which said statements were false and misleading in that said drug in the average man in his late forties would not stimulate growth and development of the sex organs and of the male sex characteristics, such as distribution of hair, muscular development and depth of voice; that said drug would not correct lack of sexual power and impotence, said drug would not relieve and postpone the many conditions associated with middle age and would not

improve the sense of well being; said drug would not constitute an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; the use of said drug would not result in improved physical and mental work and would not exert a tonic action resulting in renewed vigor; and said drug would not impart a better attitude towards social life and would not cause nervousness, exhaustion and melancholy to disappear;

That said act of causing the aforementioned circular to accompany said tablets of drug as aforesaid resulted in said tablets of drug in said envelope being further misbranded within the meaning of 21 U.S.C. 352(j), in that said drug was dangerous to health when used in the dosage and with the frequency prescribed, recommended and suggested in its labeling, since each tablet of said drug contained 25 milligrams of male hormone (methyl testosterone) and the use of a drug containing 25 milligrams of male hormone in each tablet with the frequency prescribed, recommended and suggested in the labeling, to wit, as directed in the aforesaid circular, "One tablet a day," would be dangerous to health since such use of said drug may result in sterility, and such use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth;

That said act by said defendant of causing said circular to accompany said tablets of drug as afore-

said, was an act done by said defendant while said drug was being held for sale after shipment in interstate commerce as aforesaid, which resulted in said tablets of [280] drug in said envelope being misbranded as aforesaid in violation of 21 U.S.C. 331(k). [281]

Count V.

[21 U.S.C., 331(k), 333(a), and 352(j)]

The United States Attorney further charges:

That Roche-Organon, Inc., trading and doing business at Nutley, State of New Jersey, did, on or about August 6, 1947, ship in interstate commerce from Nutley, State of New Jersey, to Los Angeles, State of California, consigned to the Mote Company, a bottle containing a number of tablets of a drug, to wit, methyl testosterone;

That thereafter, to wit, on or about August 27, 1947, the said Mote Company did sell and deliver to M. A. Clemens Pharmacy at Los Angeles, State of California, said bottle containing said tablets of drug;

That thereafter, to wit, on or about November 18, 1947, and while said tablets of drug contained in said bottle were being held for sale after shipment in interstate commerce at the said M. A. Clemens Pharmacy at Los Angeles, State of California, Martin A. Clemens, an individual, trading and doing business as M. A. Clemens Pharmacy at Los Angeles, State of California, the defendant herein, did at Los Angeles, State of California, within the Central Division of the Southern District of California,

cause to be removed a quantity of said drug, namely, 5 tablets, from said bottle and did cause to be repacked said 5 tablets of said drug so removed into an envelope and did cause to be sold and disposed of said envelope containing said tablets of said drug to one Robert C. Brandenburg solely upon the surrender by said Robert C. Brandenburg of money in payment therefor;

That displayed upon said tablets when repacked as aforesaid, was the following labeling:

Male Hormone

Each tablet contains 25 mg. testosterone the form of the true male sex hormone which is most highly effective for administration by mouth. The availability of methyl testosterone makes possible the convenience of oral administration in [282] applying androgenic therapy. The oral dose of methyl testosterone is about 1-2 tablets daily.

Trial Size	\$ 2.00
Box 30 Tablets.....	10.00
Box 60 Tablets.....	19.00
Box 100 Tablets Professional Size	29.95

Send Mail Orders to M. A. Clemens (Pharmacist)
426 So. Spring St., Room 502-503 MAdison 6-4171

Los Angeles 13, Calif.

That said act of causing the removal, repacking and disposal as aforesaid resulted in said tablets of drug in said envelope being misbranded within the meaning of 21 U.S.C. 352(j), in that said drug was

dangerous to health when used in the dosage and with the frequency prescribed, recommended and suggested in its labeling, since each tablet of said drug contained 25 milligrams of male hormone (methyl testosterone) and the use of a drug containing 25 milligrams of male hormone in each tablet with the frequency prescribed, recommended and suggested in the labeling, to wit, as directed on the label, "1-2 tablets daily" would be dangerous to health since such use of said drug may result in sterility, and such use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth;

That said act by said defendant of causing the removal from said bottle repacking into said envelope and disposal of said tablets of drug as aforesaid, was an act done by said defendant while said drug was being held for sale after shipment in interstate commerce as aforesaid, which resulted in said tablets of drug in said envelope being misbranded as aforesaid in violation of 21 U.S.C. 331(k). [283]

Count VI.

[21 U.S.C. 331(k), 333(a), 352(a) and 352(j)]

The United States Attorney further charges:

That Schering Corporation, trading and doing business at Bloomfield, State of New Jersey, did, on or about October 10, 1947, ship in interstate commerce from Bloomfield, State of New Jersey, to Los Angeles, State of California, consigned to Forum

Drug Co., a carton containing a number of tablets of a drug, to wit, methyl testosterone;

That thereafter, to wit, on or about October 16, 1947, the said Forum Drug Co., did sell and deliver to M. A. Clemens Pharmacy at Los Angeles, State of California, said carton containing said tablets of drug;

That thereafter, to wit, on or about October 27, 1947, and while said tablets of drug contained in said carton were being held for sale after shipment in interstate commerce at the said M. A. Clemens Pharmacy at Los Angeles, State of California, Martin A. Clemens, an individual, trading and doing business as M. A. Clemens Pharmacy at Los Angeles, State of California, the defendant herein, did at Los Angeles, State of California, within the Central Division of the Southern District of California, cause to be removed a quantity of said drug, namely, 5 tablets, from said carton and did cause to be repacked said 5 tablets of said drug so removed into an envelope and did cause to be sold and disposed of said envelope containing said tablets of said drug to one Allan T. Spiher, Jr., solely upon the surrender by said Allan T. Spiher, Jr., of money in payment therefor;

That displayed upon said tablets when repacked as aforesaid was the following labeling:

Male Hormone

Each tablet contains 25 mg. testosterone the form of the true male sex hormone which is most highly effective for administration by mouth. The avail-

ability of methyl testosterone [284] makes possible the convenience of oral administration in applying androgenic therapy. The oral dose of methyl testosterone is about 1-2 tablets daily.

Trial Size	\$ 2.00
Box 30 Tablets.....	10.00
Box 60 Tablets.....	19.00
Box 100 Tablets Professional Size	29.95

Send Mail Orders to M. A. Clemens (Pharmacist)
426 So. Spring St., Room 502-503 MADison 6-4171

Los Angeles 13, Calif.

That on or about October 27, 1947, and while said tablets of drug were held for sale after shipment in interstate commerce as aforesaid, the said Martin A. Clemens, did at Los Angeles, State of California, cause certain additional labeling relating to said drug, namely, a circular entitled "Male and Female Sex Hormones," to accompany said tablets of drug;

That said act of causing the aforementioned circular to accompany said tablets of drug as aforesaid resulted in said tablets of drug in said envelope being misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid labeling of said drug contained statements which represented and suggested that said drug would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development and depth of voice; that said drug would correct lack of sexual power and impotence; that said drug would relieve and post-

pone the many conditions associated with middle age and would improve the sense of well being; that said drug constituted an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; that the use of said drug would result in improved physical and mental work and would exert a tonic action resulting in renewed vigor; and that said drug would impart a better attitude towards [285] social life and would cause nervousness, exhaustion and melancholy to disappear in the average man in his late forties, which said statements were false and misleading in that said drug in the average man in his late forties would not stimulate growth and development of the sex organs and of the male sex characteristics, such as distribution of hair, muscular development and depth of voice; that said drug would not correct lack of sexual power and impotence, said drug would not relieve and postpone the many conditions associated with middle age and would not improve the sense of well being; said drug would not constitute an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; the use of said drug would not result in improved physical and mental work and would not exert a tonic action resulting in renewed vigor; and said drug would not impart a better attitude towards social life and

would not cause nervousness, exhaustion, and melancholy to disappear;

That said act of causing the aforementioned circular to accompany said tablets of drug as aforesaid resulted in said tablets of drug in said envelope being further misbranded within the meaning of 21 U.S.C. 352(j), in that said drug was dangerous to health when used in the dosage and with the frequency prescribed, recommended and suggested in its labeling, since each tablet of said drug contained 25 milligrams of male hormone (methyl testosterone) and the use of a drug containing 25 milligrams of male hormone in each tablet with the frequency prescribed, recommended and suggested in the labeling, to wit, as directed in the aforesaid circular, "One tablet a day," would be dangerous to health since such use of said drug may result in sterility, and such use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth;

That said act by said defendant of causing said circular to accompany said tablets of drug as aforesaid, was an act done by said defendant while said drug was being held for sale after shipment [286] in interstate commerce as aforesaid, which resulted in said tablets of drug in said envelope being misbranded as aforesaid in violation of 21 U.S.C. 331(k). [287]

Count VII.

[21 U.S.C. 331 (k), 333(a) and 352 (j)]

The United States Attorney further charges:

That Schering Corporation, trading and doing business at Bloomfield, State of New Jersey, did, on or about October 10, 1947, ship in interstate commerce from Bloomfield, State of New Jersey, to Los Angeles, State of California, consigned to Forum Drug Co., a carton containing a number of tablets of a drug, to wit, methyl testosterone;

That thereafter, to wit, on or about October 16, 1947, the said Forum Drug Co., did sell and deliver to M. A. Clemens Pharmacy at Los Angeles, State of California, said carton containing said tablets of drug;

That thereafter, to wit, on or about October 27, 1947, and while said tablets of drug contained in said carton were being held for sale after shipment in interstate commerce at the said M. A. Clemens Pharmacy at Los Angeles, State of California, Martin A. Clemens, an individual, trading and doing business as M. A. Clemens Pharmacy at Los Angeles, State of California, the defendant herein, did at Los Angeles, State of California, within the Central Division of the Southern District of California, caused to be removed a quantity of said drug, namely, 5 tablets, from said carton and did cause to be repacked said 5 tablets of said drug so removed into an envelope and did cause to be sold and disposed of said envelope containing said tablets of said drug to one Allan T. Spiher, Jr., solely upon the

surrender by said Allan T. Spiher, Jr., of money in payment therefore;

That displayed upon said tablets when repacked as aforesaid was the following labeling:

Male Hormone

Each tablet contains 25 mg. testosterone the form of the true male sex hormone which is most highly effective for administration by mouth. The availability of methyl testosterone [288] makes possible the convenience of oral administration in applying androgenic therapy. The oral dose of methyl testosterone is about 1-2 tablets daily.

Trial Size	\$ 2.00
Box 30 Tablets.....	10.00
Box 60 Tablets.....	19.00
Box 100 Tablets Professional Size	29.95

Send Mail Orders to M. A. Clemens (Pharmacist)
426 So. Spring St., Room 502-503 MADison 6-4171

Los Angeles 13, Calif.

That said act of causing the removal, repacking and disposal as aforesaid resulted in said tablets of drug in said envelope being misbranded within the meaning of 21 U.S.C. 352(j), in that said drug was dangerous to health when used in the dosage and with the frequency prescribed, recommended and suggested in its labeling, since each tablet of said drug contained 25 milligrams of male hormone (methyl testosterone) and the use of a drug containing 25 milligrams of male hormone in each tablet with the frequency prescribed, recommended and

suggested in the labeling, to wit, as directed on the label, "1-2 tablets daily" would be dangerous to health since such use of said drug may result in sterility, and such use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth;

That said act by said defendant of causing the removal from said bottle repacking into said envelope and disposal of said tablets of drug as aforesaid, was an act done by said defendant while said drug was being held for sale after shipment in interstate commerce as aforesaid, which resulted in said tablets of drug in said envelope being misbranded as aforesaid in violation of 21 U.S.C. 331(k). [289]

Count VIII.

[21 U.S.C. 331(k), 333(a), 352(a), and 352(j)]

The United States Attorney further charges:

That Ciba Pharmaceutical Products, Inc., trading and doing business at Summit, State of New Jersey, did, on or about November 13, 1947, ship in interstate commerce from Summit, State of New Jersey, to Los Angeles, State of California, consigned to El-O-Pathic Pharmacy, Inc., a bottle containing a number of tablets of a drug, to wit, methyl testosterone;

That thereafter, to wit, on or about November 20, 1947, and while said tablets of drug contained in said bottle were being held for sale after shipment in interstate commerce as aforesaid at the said El-O-Pathic Pharmacy, Inc., at Los Angeles, State of California, the said El-O-Pathic Pharmacy, Inc., a

corporation, organized and existing under the laws of the State of California and trading and doing business at Los Angeles, State of California, and Martin A. Clemens, manager and director of said corporation, the defendants herein, did at Los Angeles, State of California, within the Central Division of the Southern District of California caused to be removed a quantity of said drug, namely, 5 tablets, and did cause to be repacked said 5 tablets of said drug so removed into an envelope and did cause to be sold and disposed of said envelope containing said tablets of said drug to one Alan T. Spiher, solely upon the surrender by said Alan T. Spiher of money in payment therefore;

That displayed upon said tablets when repacked as aforesaid was the following label:

Male Hormone

Each tablet contains 25 mg. testosterone the form of the true male sex hormone which is most highly effective for administration by mouth. The availability of methyl testosterone makes possible the convenience of oral administration in applying androgenic therapy. The oral dose of methyl testosterone [290] is about 1-2 tablets daily.

Trial Size	\$ 2.00
Box 30 Tablets.....	10.00
Box 60 Tablets.....	19.00
Box 100 Tablets Professional Size	29.95

Send Mail Orders to El-O-Pathic Pharmacy
11091½ No. Western Ave. Hollywood 1722

Hollywood 27, Calif.

Note: Please understand this trial size is simply an introductory package and for marked results treatment must be continued over a 30-day period.

That on or about November 20, 1947, and while said tablets of drug were held for sale after shipment in interstate commerce as aforesaid, the said El-O-Pathic Pharmacy, Inc., and Martin A. Clemens, the defendants herein, did at Los Angeles, State of California, cause certain additional labeling relating to said drug, namely, a circular entitled "Male and Female Sex Hormones," to accompany said tablets of drug;

That said acts of causing the aforementioned circular to accompany said tablets of drug as aforesaid resulted in said tablets of drug in said envelope being misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid labeling of said drug contained statements which represented and suggested that said drug would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development and depth of voice; that said drug would correct lack of sexual power and impotence; that said drug would relieve and postpone the many conditions associated with middle age and would improve the sense of well being; that said drug constituted an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade [291] them, nervousness, depression, general weakness and lack of physical strength; that the use of said drug would result in improved physical and mental work and

would exert a tonic action resulting in renewed vigor; and that said drug would impart a better attitude towards social life and would cause nervousness, exhaustion and melancholy to disappear in the average man in his late forties, which said statements were false and misleading in that said drug in the average man in his late forties, would not stimulate growth and development of the sex characteristics such as distribution of hair, muscular development and depth of voice; said drug would not correct lack of sexual power and impotence; said drug would not relieve and postpone the many conditions associated with middle age and would not improve the sense of well being; said drug would not constitute an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; the use of said drug would not result in improved physical and mental work and would not exert a tonic action resulting in renewed vigor; and said drug would not impart a better attitude toward social life and would not cause nervousness, exhaustion and melancholy to disappear;

That said acts of causing the aforementioned circular to accompany said tablets of drug as afore-said resulted in said tablets of drug in said envelope being further misbranded within the meaning of 21 U.S.C. 352(j), in that said drug was dangerous to health when used in the dosage and with the fre-

quency prescribed, recommended and suggested in its labeling, since each tablet of said drug contained 25 milligrams of male hormone (methyl testosterone) and the use of a drug containing 25 milligrams of male hormone in each tablet with the frequency prescribed, recommended and suggested in the labeling, to wit, as directed in the aforesaid circular, "One tablet a day," would be dangerous to health since use of said drug may result in sterility, and such use by [292] individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth;

That said acts by said defendants of causing said circular to accompany said tablets of drug as aforesaid were acts done by said defendants while said drug was being held for sale after shipment in interstate commerce as aforesaid, which resulted in said tablets of drug in said envelope being misbranded as aforesaid in violation of 21 U.S.C. 331(k). [293]

Count IX.

[21 U.S.C. 331(k), 333(a) and 352(j)]

The United States Attorney further charges:

That Ciba Pharmaceutical Products, Inc., trading and doing business at Summit, State of New Jersey, did, on or about November 13, 1947, ship in interstate commerce from Summit, State of New Jersey, to Los Angeles, State of California, consigned to El-O-Pathic Pharmacy, Inc., a bottle containing a number of tablets of a drug, to wit, methyl testosterone;

That thereafter, to wit, on or about November 20, 1947, and while said tablets of drug contained in said bottle were being held for sale after shipment in interstate commerce as aforesaid at the said El-O-Pathic Pharmacy, Inc., at Los Angeles, State of California, the said El-O-Pathic Pharmacy, Inc., a corporation, organized and existing under the laws of the State of California and trading and doing business at Los Angeles, State of California, and Martin A. Clemens, manager and director of said corporation, the defendants herein, did at Los Angeles, State of California, within the Central Division of the Southern District of California cause to be removed a quantity of said drug, namely, 5 tablets, and did cause to be repacked said 5 tablets of said drug so removed into an envelope and did cause to be sold and disposed of said envelope containing said tablets of said drug to one Alan T. Spiher, solely upon the surrender by said Alan T. Spiher of money in payment therefor;

That displayed upon said tablets when repacked as aforesaid was the following labeling:

Male Hormone

Each tablet contains 25 mg. testosterone the form of the true male sex hormone which is most highly effective for administration by mouth. The availability of methyl testosterone makes possible the convenience of oral administration in applying androgenic therapy. The oral dose of methyl testosterone [294] is about 1-2 tablets daily.

Trial Size	\$ 2.00
Box 30 Tablets.....	10.00
Box 60 Tablets.....	19.00
Box 100 Tablets Professional Size	29.95

Send Mail Orders to El-O-Pathic Pharmacy

1109½ No. Western Ave.

Hollywood 1722

Hollywood 27, Calif.

Note: Please understand this trial size is simply an introductory package and for marked results treatment must be continued over a 30-day period.

That said acts of causing the removal, repacking and disposal as aforesaid resulted in said tablets of drug in said envelope being misbranded within the meaning of 21 U.S.C. 352(j), in that said drug was dangerous to health when used in the dosage and with the frequency prescribed, recommended and suggested in its labeling, since each tablet of said drug contained 25 milligrams of male hormone (methyl testosterone) and the use of a drug containing 25 milligrams of male hormone in each tablet with the frequency prescribed, recommended and suggested in the labeling, to wit, as directed on the label, "1-2 tablets daily" would be dangerous to health since such use of said drug may result in sterility, and such use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth;

That said acts by said defendants of causing the removal from said bottle repacking into said envelope and disposal of said tablets of drug as aforesaid, were acts done by said defendants while said drug

was being held for sale after shipment in interstate commerce as aforesaid, which resulted in said tablets of drug in said envelope being misbranded as aforesaid in violation of 21 U.S.C. 331(k). [295]

Count X.

[21 U.S.C. 331(a), 333(a), 352(b)(2), 352(e)(1), 352(f)(1) and 352(f)(2)]

The United States Attorney further charges:

That Martin A. Clemens, an individual, trading and doing business under the firm name M. A. Clemens Pharmacy at Los Angeles, State of California, did, within the Central Division of the Southern District of California, on or about October 26, 1947, in violation of the Federal Food, Drug, and Cosmetic Act, unlawfully cause to be introduced and delivered for introduction into interstate commerce at Los Angeles, State of California, for delivery to Phoenix, State of Arizona, consigned to Helen Thompson, a box containing a number of tablets of a drug;

That displayed upon said box was the following labeling:

Female

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was misbranded within the meaning of 21 U.S.C. 352(b)(2), in that said drug was in package form and it failed to bear a label containing an accurate statement of the quantity of

the contents, to wit, the label of said drug bore no statement of the quantity of the contents;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 352(e)(1), in that it was a drug not designated solely by a name recognized in an official compendium and its label failed to bear the common or usual name of the drug;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 352(f)(1), in that the labeling of said drug failed to bear adequate directions for use, to wit, the labeling of said drug bore no directions for use; [296]

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 352(f)(2), in that the labeling of said drug failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health in such manner and form as are necessary for the protection of users in that each tablet of said drug contained 0.5 milligrams of alphaestradiol and the labeling of said drug failed to warn that its unrestricted use may result in injury to the female generative system and that its use by females with early and incipient carcinoma of the breast, cervix and uterus may result in acceleration of the malignant growth. [297]

Count XI.

[21 U.S.C. 331(a), 333(a), 352(a), 352(f)(2) and 352(j)]

The United States Attorney further charges:

That El-O-Pathic Pharmacy, Inc., a corporation, organized and existing under the laws of the State of California, and trading and doing business at Los Angeles, State of California, and Martin A. Clemens, an individual, at the time hereinafter mentioned manager and director of said corporation, did, within the Central Division of the Southern District of California on or about December 8, 1947, in violation of the Federal Food, Drug, and Cosmetic Act, unlawfully cause to be introduced and delivered for introduction into interstate commerce at Los Angeles, State of California, for delivery to Phoenix, State of Arizona, consigned to William E. Bryner, a box containing a number of tablets of a drug;

That displayed upon said box was the following labeling:

Male Hormone

Each tablet contains 25 mg. testosterone the form of the true male sex hormone which is most highly effective for administration by mouth. The availability of methyl testosterone makes possible the convenience of oral administration in applying an-

drogenic therapy. The oral dose of methyl testosterone is about 1-2 tablets daily.

Trial Size	\$ 2.00
Box 30 Tablets.....	10.00
Box 60 Tablets.....	19.00
Box 100 Tablets Professional Size...	29.95

Send Mail Orders to El-O-Pathic Pharmacy
1109½ No. Western Ave. Hollywood 1722
Hollywood 27, Calif.

Note: Please understand this trial size is simply an introductory package and for marked results, treatment must be continued over a 30-day period.

That accompanying said drug was certain additional labeling relating to said drug, namely, a circular entitled, "Male and Female Sex Hormones";

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid labeling of said drug contained statements which represented and suggested that said drug would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development and depth of voice; that said drug would correct lack of sexual power and impotence; that said drug would relieve and postpone the many conditions associated with middle age and would improve the sense of well being; that said drug constituted an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness

and lack of physical strength; that the use of said drug would result in improved physical and mental work and would exert a tonic action resulting in renewed vigor; and that said drug would impart a better attitude toward social life and would cause nervousness, exhaustion and melancholy to disappear in the average man in his late forties, which said statements were false and misleading in that said drug in the average man in his late forties, would not stimulate growth and development of the sex organs and of the male sex characteristics, such as distribution of hair, muscular development and depth of voice; said drug would not correct lack of sexual power and impotence; said drug would not relieve and postpone the many conditions associated with middle age and would not improve the sense of well being; said drug would not constitute an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness [299] depression, general weakness and lack of physical strength; the use of said drug would not result in improved physical and mental work and would not exert a tonic action resulting in renewed vigor; and said drug would not impart a better attitude towards social life and would not cause nervousness, exhaustion and melancholy to disappear;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 352(f)(2), in that the labeling of said drug failed to bear such adequate warnings against use in those pathological conditions where

its use may be dangerous to health in such manner and form as are necessary for the protection of users, in that each tablet of said drug contained 25 milligrams of male hormone (methyl testosterone) and the labeling of said drug failed to warn that its use may result in sterility and its use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U. S. C. 352(j), in that said drug was dangerous to health when used in the dosage and with the frequency prescribed, recommended and suggested in its labeling, since each tablet of said drug contained 25 milligrams of male hormone (methyl testosterone) and the use of a drug containing 25 milligrams of male hormone in each tablet with the frequency prescribed, recommended and suggested in the labeling, to wit, as directed on the box label, "1-2 tablets daily" and as directed in the aforesaid circular, "One tablet a day," would be dangerous to health since such use of said drug may result in sterility, and such use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth.

Count XII.

[21 U.S.C. 331(a), 333(a), 352(a), 352(f)(1) and 352(f)(2)]

The United States Attorney further charges:

That El-O-Pathic Pharmacy, Inc., a corporation,

organized and existing under the laws of the State of California, and trading and doing business at Los Angeles, State of California, and Martin A. Clemens, an individual, at the time hereinafter mentioned manager and director of said corporation, did, within the Central Division of the Southern District of California on or about January 9, 1948, in violation of the Federal Food, Drug, and Cosmetic Act, unlawfully cause to be introduced and delivered for introduction into interstate commerce at Los Angeles, State of California, for delivery to Tucson, State of Arizona, consigned to Joe Smith, a bottle containing a number of linguets of a drug;

That displayed upon said bottle was the following labeling:

75

Metandren Linguets

Trade Mark Reg. U.S. Pat. Off.

Compressed wafers especially designed for absorption from under the tongue or inside the Cheek.

Each linguet contains 5 mg. of Metandren (methyltestosterone), orally active androgen. Caution: To be dispensed only by or on the prescription of a physician.

C

B A

Ciba Pharmaceutical Products, Inc.,

Summit, New Jersey

Literature describing this product is available to physicians upon request.

Made in U.S.A.

2284

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Distributed By El-O-Pathic Company

1109½ No. Western Ave. Los Angeles 27, Calif.

That accompanying said drug was certain additional labeling relating to said drug, namely, a circular entitled, "Male and Female Sex Hormones";

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid labeling of said drug contained statements which represented and suggested that said drug would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development and depth of voice; that said drug would correct lack of sexual power and impotence; that said drug would relieve and postpone the many conditions associated with middle age and would improve the sense of well being; that said drug constituted an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; that the use of said drug would result in improved physical and mental work and would exert a tonic action result-

ing in renewed vigor; and that said drug would impart a better attitude toward social life and would cause nervousness, exhaustion and melancholy to disappear in the average man in his late forties, which said statements were false and misleading in that said drug in the average man in his late forties, would not stimulate [302] growth and development of the sex organs and of the male sex characteristics, such as distribution of hair, muscular development and depth of voice; said drug would not correct lack of sexual power and impotence; said drug would not relieve and postpone the many conditions associated with middle age and would not improve the sense of well being; said drug would not constitute an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; the use of said drug would not result in improved physical and mental work and would not exert a tonic action resulting in renewed vigor; and said drug would not impart a better attitude towards social life and would not cause nervousness, exhaustion and melancholy to disappear;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 352(f)(1), in that the labeling of said drug failed to bear adequate directions for use, to wit, the labeling of said drug bore no directions for use;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce

as aforesaid was further misbranded within the meaning of 21 U.S.C. 352(f)(2), in that the labeling of said drug failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users, in that each linguet of said drug contained 5 milligrams of male hormone (methyl testosterone) and the labeling of said drug failed to warn that its unrestricted use may result in sterility and unrestricted use of said drug by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth. [303]

Count XIII.

[21 U.S.C. 331(a), 333(a), 352(a), 352(f)(2) and 352(j)]

The United States Attorney further charges:

That Martin A. Clemens, an individual, trading and doing business under the firm name M. A. Clemens Pharmacy at Los Angeles, State of California, did, within the Central Division of the Southern District of California, on or about January 19, 1948, in violation of the Federal Food, Drug, and Cosmetic Act, unlawfully cause to be introduced and delivered for introduction into interstate commerce at Los Angeles, State of California, for delivery to Tucson, State of Arizona, consigned to D. J. McBride, a bottle containing a number of linguets of a drug;

That displayed upon said bottle was the following labeling:

Male Hormone

Each tablet contains 5 mg. testosterone the form of the true male hormone which is most highly effective for administration by mouth. The availability of methyl testosterone makes possible the convenience of oral administration in applying androgenic therapy.

The oral dose of methyl testosterone is 2 tablets daily. Place 2 tablets under the tongue and allow them to dissolve.

Box 50 Tablets Linguets	\$ 7.00
Box 100 Tablets Linguets	13.00

Send Mail Orders to

M. A. Clemens (Pharmacist)

426 So. Spring St., Room 502-503,
Los Angeles, 13, Calif.

Successor to Clark's Drugs & Sundries

That accompanying said drug, was certain additional labeling relating to said drug, namely, a circular entitled "Male and Female Sex Hormones";

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was misbranded [304] within the meaning of 21 U.S.C. 352(a), in that the aforesaid labeling of said drug contained statements which represented and suggested that said drug would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development and depth of

voice; that said drug would correct lack of sexual power and impotence; that said drug would relieve and postpone the many conditions associated with middle age and would improve the sense of well being; that said drug constituted an adequate treatment for flushes, sweats, and chills, impaired memory, in ability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; that the use of said drug would result in improved physical and mental work and would exert a tonic action resulting in renewed vigor; and that said drug would impart a better attitude toward social life and would cause nervousness, exhaustion and melancholy to disappear in the average man in his late forties, which said statements were false and misleading in that said drug in the average man in his late forties, would not stimulate growth and development of the sex organs and of the male sex characteristics, such as distribution of hair, muscular development and depth of voice; said drug would not correct lack of sexual power and impotence; said drug would not relieve and postpone the many conditions associated with middle age and would not improve the sense of well being; said drug would not constitute an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; the use of said drug would not result in improved physical and mental work and would not exert a tonic action re-

sulting in renewed vigor; and said drug would not impart a better attitude towards social life and would not cause nervousness, exhaustion and melancholy to disappear; [305]

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 353(f)(2), in that the labeling of said drug failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health and against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users, in that each linguet of said drug contained 5 milligrams of male hormone (methyl testosterone) and the labeling of said drug failed to warn that its use may result in sterility and its use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 352(j), in that said drug was dangerous to health, when used in the dosage and with the frequency prescribed, recommended and suggested in its labeling since each linguet of said drug contains 5 milligrams of male hormone (methyl testosterone) and the use of a drug containing 5 milligrams of male hormone in each linguet, with the frequency prescribed, recommended and suggested in the labeling, to wit, as directed on the

bottle label, "2 tablets 3 times daily," would be dangerous to health, since such use of said drug may result in sterility, and such use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth. [306]

Count XIV.

[21 U.S.C. 331(a), 333(a), 352(a), 352(f)(1), and 352(f)(2)]

The United States Attorney further charges:

That El-O-Pathic Pharmacy, Inc., a corporation, organized and existing under the laws of the State of California, and trading and doing business at Los Angeles, State of California, and Martin A. Clemens, an individual, at the time hereinafter mentioned manager and director of said corporation, did, within the Central Division of the Southern District of California on or about November 6, 1947, in violation of the Federal Food, Drug, and Cosmetic Act, unlawfully cause to be introduced and delivered for introduction into interstate commerce at Los Angeles, State of California, for delivery to Seattle, State of Washington, consigned to Robert N. Diehl, a bottle containing a number of linguets of a drug;

That displayed upon said bottle was the following labeling:

100 Metandren Linguets

Trade Mark Reg. U.S. Pat. Off.

Compressed wafers especially designed for absorption from under the tongue or inside the cheek.

Each linguet contains 5 mg. of Metandren (methyl testosterone), orally active androgen. Caution: To be dispensed only by or on the prescription of a physician.

C

B A

Ciba Pharmaceutical Products, Inc.

Summit, New Jersey

Literature describing this product is available to physicians upon request.

Made in U.S.A.

2284

111177

That accompanying said drug was certain additional labeling relating to said drug, namely, a circular entitled, "Male and Female Sex Hormones";

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid labeling of said drug contained statements which represented and suggested that said drug would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development and depth of voice; that said drug would correct lack of sexual power and impotence; that said drug would relieve and postpone the many conditions associated with middle age and would improve the sense of well being; that said drug constituted an adequate treatment for flushes, sweats, and chills, impaired memory, inability to

concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; that the use of said drug would result in improved physical and mental work and would exert a tonic action resulting in renewed vigor; and that said drug would impart a better attitude toward social life and would cause nervousness, exhaustion and melancholy to disappear in the average man in his late forties, which said statements were false and misleading in that said drug in the average man in his late forties, would not stimulate growth and development of the sex organs and of the male sex characteristics, such as distribution of hair, muscular development and depth of voice; said drug would not correct lack of sexual power [308] and impotence; said drug would not relieve and postpone the many conditions associated with middle age and would not improve the sense of well being; said drug would not constitute an adequate treatment for flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; the use of said drug would not result in improved physical and mental work and would not exert a tonic action resulting in renewed vigor; and said drug would not impart a better attitude towards social life and would not cause nervousness, exhaustion and melancholy to disappear;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the

meaning of 21 U.S.C. 352(f)(1), in that the labeling of said drug failed to bear adequate directions for use, to wit, the labeling of said drug bore no directions for use;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid was further misbranded within the meaning of 21 U.S.C. 352(f)(2), in that the labeling of said drug failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users, in that each linguet of said drug contained 5 milligrams of male hormone (methyl testosterone) and the labeling of said drug failed to warn that its unrestricted use may result in sterility and unrestricted use of said drug by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth.

/s/ JAMES M. CARTER,

United States Attorney.

By /s/ ARLINE MARTIN,

Assistant U. S. Attorney.

[Endorsed]: Filed March 22, 1949. [309]

[Title of District Court and Cause No. 20642.]

INFORMATION

(21 U.S.C. 331 and 333)

Introduction Into Interstate Commerce
of Misbranded Drugs

Count I.

[21 U.S.C. 331(a), 333(a), 352(a), 352(f)(1)]

The United States Attorney charges:

That Allen H. Parkinson, an individual, trading and doing business under the firm name of Hudson Products Company, at Long Beach, State of California, did, within the Central Division of the Southern District of California, on or about February 27, 1948, in violation of the Federal Food, Drug, and Cosmetic Act, unlawfully cause to be introduced and delivered for introduction into interstate commerce at Long Beach, State of California, for delivery to Altoona, Commonwealth of Pennsylvania, consigned to Roy H. Downing, a carton containing a number of tablets of a drug;

That displayed upon said carton was the following labeling:

Male Sex Hormones

(30) 10 Mg. Methyl-Testosterone Tablets

Dosage: 1 Tablet Daily

Important—In case of pronounced male sex hormone deficiency take 3 tablets daily [367] for 10 days. After the 10 day period take 1 tablet daily.

Caution: Take Only as Directed

Hudson Products Co.

341 Harding Street

Long Beach 5, Calif.

That accompanying said drug was certain additional labeling relating to said drug, namely, a leaflet entitled "The Male Hormone";

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid leaflet entitled "The Male Hormone" contained statements which represented and suggested that said drug was the true male sex hormone and that said drug in the average man in his late forties would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development and depth of voice; that said drug would correct lack of sexual power and impotence; that said drug would relieve and postpone the many conditions associated with middle age and would improve the sense of well being; that said drug would be efficacious in the treatment of flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; that the use of said drug would result in improved physical and mental work and would exert a tonic action resulting in renewed vigor; and that said drug would impart a better attitude toward social life and would cause nervousness, exhaustion and melancholy to disappear, which said statements were false and misleading in that said drug was not the true male sex hormone and said drug in the average man in his late forties, would not stimulate growth

and development of the sex organs and of the male sex characteristics, such as distribution of hair, muscular development and depth of voice; said drug would not correct lack of sexual power and impotence; said drug would not relieve and postpone the many conditions associated [368] with middle age and would not improve the sense of well being; said drug would not be efficacious in the treatment of flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; the use of said drug would not result in improved physical and mental work and would not exert a tonic action resulting in renewed vigor; and said drug would not impart a better attitude towards social life and would not cause nervousness, exhaustion and melancholy to disappear;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 352(f)(1), in that the labeling of said drug failed to bear adequate directions for use, in that the directions for use, to wit, "Dosage: 1 tablet daily Important—In case of pronounced male sex hormone deficiency take 3 tablets daily for ten days. After 10 day period take 1 tablet daily," on the labeling of said drug were not adequate directions for use. [369]

Count II.

[21 U.S.C. 331(a), 333(a), 352(a), 352(f)(1)]

The United States Attorney further charges:

That Allen H. Parkinson, an individual, trading and doing business under the firm name of Hudson Products Company, at Long Beach, State of California, did, within the Central Division of the Southern District of California, on or about June 15, 1948, in violation of the Federal Food, Drug, and Cosmetic Act, unlawfully cause to be introduced and delivered for introduction into interstate commerce at Long Beach, State of California, for delivery to Chicago, State of Illinois, consigned to Charles Dank, a carton containing a number of tablets of a drug;

That displayed upon said carton was the following labeling:

Male Sex Hormones

(30) 10 Mg. Methyl-Testosterone Tablets

Suggested Dosage: 1 Tablet Daily

Important: In case of pronounced male sex hormone deficiency take 3 tablets daily before eating for 10 days. After the 10 day period take 1 tablet daily before meals or as directed by your physician.

Warning: The male sex hormone should be carefully used by elderly men with cardiovascular disturbances and should not be used if there is any indication of cancer of the prostate.

Not for use by children. Caution—take only as directed.

Hudson Products Co.

341 Harding St.

Long Beach 5, Calif.

That accompanying said drug was certain additional labeling relating to said drug, namely, a leaflet entitled "The Male Hormone";

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid leaflet entitled "The Male Hormone" contained statements which represented and suggested that said drug was the true male sex hormone and that said [370] drug in the average man in his late forties would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development and depth of voice; that said drug would correct lack of sexual power and impotence; that said drug would relieve and postpone the many conditions associated with middle age and would improve the sense of well being; that said drug would be efficacious in the treatment of flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; that the use of said drug would result in improved physical and mental work and would exert a tonic action resulting in renewed vigor; and that said drug would impart a better attitude toward social life and would cause nervousness, exhaustion and melancholy to disappear, which said statements were false and misleading in that said drug was not the true male sex hormone and said drug in the average man in his late forties,

would not stimulate growth and development of the sex organs and of the male sex characteristics, such as distribution of hair, muscular development and depth of voice; said drug would not correct lack of sexual power and impotence; said drug would not relieve and postpone the many conditions associated with middle age and would not improve the sense of well being; said drug would not be efficacious in the treatment of flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; the use of said drug would not result in improved physical and mental work and would not exert a tonic action resulting in renewed vigor; and said drug would not impart a better attitude towards social life and would not cause nervousness, exhaustion and melancholy to disappear;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 352 (f)(1), in that the labeling of said drug failed to bear adequate directions for use, in that the [371] directions for use, to wit, "Dosage: 1 tablet daily Important—In case of pronounced male sex hormone deficiency take 3 tablets daily before eating for 10 days. After the 10 day period take 1 tablet daily before meals or as directed by your physician," on the labeling of said drug were not adequate directions for use. [372]

Count III.

[21 U.S.C. 331(a), 333(a), 352(a), 352(f)(1)]

The United States Attorney further charges:

That Allen H. Parkinson, an individual, trading and doing business under the firm name of Hudson Products Company, at Long Beach, State of California, did, within the Central Division of the Southern District of California, on or about August 3, 1948, in violation of the Federal Food, Drug, and Cosmetic Act, unlawfully cause to be introduced and delivered for introduction into interstate commerce at Long Beach, State of California, for delivery to Seattle, State of Washington, consigned to Armond W. Welch, a carton containing a number of tablets of a drug;

That displayed upon said carton was the following labeling:

Male Sex Hormones

(30) 10 Mg. Methyl-Testosterone Tablets

Suggested Dosage: 1 Tablet Daily

Important: In case of pronounced male sex hormone deficiency take 3 tablets daily before eating for 10 days. After the 10 day period take 1 tablet daily before meals or as directed by your physician.

Warning: The male sex hormone should be carefully used by elderly men with cardiovascular disturbances and should not be used if there is any indication of cancer of the prostate.

Not for use by children. Caution—take only as directed.

Hudson Products Co.

341 Harding St.

Long Beach 5, Calif.

That accompanying said drug was certain additional labeling relating to said drug, namely, a leaflet entitled "The Male Hormone" and a leaflet entitled "The Story of Hormones";

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid leaflet entitled "The Male Hormone" contained statements which represented and [373] suggested that said drug was the true male sex hormone and that said drug in the average man in his late forties would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development and depth of voice; that said drug would correct lack of sexual power and impotence; that said drug would relieve and postpone the many conditions associated with middle age and would improve the sense of well being; that said drug would be efficacious in the treatment of flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; that the use of said drug would result in improved physical and mental work and would exert a tonic action resulting in renewed vigor; and that said drug would impart a better attitude toward social life and would cause nervousness, exhaustion and melancholy to disappear, which said statements were false and misleading in that said drug was not the true male sex hormone and said drug in the average man in his

late forties, would not stimulate growth and development of the sex organs and of the male sex characteristics, such as distribution of hair, muscular development and depth of voice; said drug would not correct lack of sexual power and impotence; said drug would not relieve and postpone the many conditions associated with middle age and would not improve the sense of well being; said drug would not be efficacious in the treatment of flushes, sweats, and chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness and lack of physical strength; the use of said drug would not result in improved physical and mental work and would not exert a tonic action resulting in renewed vigor; and said drug would not impart a better attitude towards social life and would not cause nervousness, exhaustion and melancholy to disappear; [374]

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid leaflet entitled "The Story of Hormones" contained statements which represented and suggested that in the average man said drug would relieve and postpone the many conditions formerly thought to be inevitable with middle age; that said drug would be efficacious in the treatment of nervous tension and intense subjective nervousness and irritability; that said drug would be efficacious in the treatment of numbness in the extremities and itching, prickling

and tingling of the skin on waking up at night; that said drug would be efficacious in the treatment of headaches; that said drug would prevent a decrease in the ability to concentrate and would remedy faulty memory; that said drug would be efficacious in the treatment of depression and melancholia; that said drug would correct a lack of interest in social and business life, lack of mental concentration, and lack of energy; that said drug would correct a feeling of inadequacy and impotency; that said drug would be efficacious in the treatment of hot flashes and feelings of smothering and sweating and chilly, creepy sensations; that said drug would prevent the user from tiring easily and gaining excessive weight; that said drug would be efficacious in the treatment of constipation, vague digestive complaints, and precordial angina pectoris-like pains; that said drug would be efficacious in the treatment of urinary symptoms, such as frequency, nocturia, dribbling, and inability to start urinary stream; that said drug would restore confidence in mental reactions and decisions, and would notably increase the user's capacity for mental and physical work and that said drug would increase potency and libido; which statements were false and misleading in that said drug in the average man would not relieve and postpone the many conditions formerly thought to be inevitable with middle age; said drug would not be efficacious in the treatment of nervous tension and intense subjective nervousness [375] and irritability, said drug would not be efficacious in the treatment of numbness in the extremities

and itching, prickling and tingling of the skin on waking up at night; said drug would not be efficacious in the treatment of headaches; said drug would not prevent a decrease in the ability to concentrate and would not remedy faulty memory; said drug would not be efficacious in the treatment of depression and melancholia; said drug would not correct a lack of interest in social and business life, lack of mental concentration, and lack of energy, said drug would not correct a feeling of inadequacy and impotency, said drug would not be efficacious in the treatment of hot flashes and feelings of smothering and sweating and chilly, creepy sensations; said drug would not prevent the user from tiring easily and gaining excessive weight; said drug would not be efficacious in the treatment of constipation, vague digestive complaints and precordial angina pectoris-like pains; said drug would not be efficacious in the treatment of urinary symptoms, such as frequency, nocturia, dribbling, and inability to start urinary stream; said drug would not restore confidence in mental reactions and decisions, and would not notably increase the user's capacity for mental and physical work; and said drug would not increase potency, and libido;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 21 U.S.C. 352(f)(1), in that the labeling of said drug failed to bear adequate directions for use, in that the directions for use, to wit, "Dosage: 1 tablet daily. Important: In case of pronounced

male sex hormone deficiency take 3 tablets daily before eating for 10 days. After the 10-day period take 1 tablet daily before meals or as directed by your physician," on the labeling of said drug, were not adequate directions for use. [376]

Count IV.

[21 U.S.C. 331(a), 333(a), 352(a), 352(f)(1), 352(f)(2), 352(j)]

The United States Attorney further charges:

That Allen H. Parkinson, an individual, trading and doing business under the firm name of Hudson Products Company, at Long Beach, State of California, did, within the Central Division of the Southern District of California, on or about August 3, 1948, in violation of the Federal Food, Drug, and Cosmetic Act, unlawfully cause to be introduced and delivered for introduction into interstate commerce at Long Beach, State of California, for delivery to Seattle, State of Washington, consigned to Armond M. Welch, a carton containing a number of tablets of a drug;

That displayed upon said carton was the following labeling:

Female Hormones

(30) 0.1 Mg. Cryst. a-Estradiol

Important: In case of pronounced female sex hormone deficiency take 3 tablets daily before meals for 10 days. After the 10-day period take 1 tablet daily or as directed by your physician.

Warning: The female hormone should not be used by women with cancer or pre-cancerous lesions of the breast or genital organs.

Not for use by children. Caution—take only as directed.

Hudson Products Co.

341 Harding St.

Long Beach 5, Calif.

That accompanying said drug was certain additional labeling relating to said drug, namely, a leaflet entitled "The Male Hormone," and a leaflet entitled "The Story of Hormones";

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was misbranded within the meaning of 21 U.S.C. 352(a), in that the aforesaid leaflets contained statements which represented and suggested that said drug, in women, would relieve and postpone the conditions associated with middle age; that said drug would bring prompt relief from hot flashes, emotional disturbances and other manifestations associated with the menopause; that said drug would be efficacious to [377] bring about a steady readjustment and to help overcome most menopausal conditions in woman approaching or passing through the menopause, which statements were false and misleading in that said drug would not be efficacious in woman to relieve and postpone the conditions associated with middle age; said drug would not bring prompt relief from hot flashes, emotional disturbances and other manifestations associated with

the menopause; and said drug would not be efficacious to bring about a steady readjustment and to help overcome most menopausal conditions in woman approaching or passing through the menopause;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 352(f)(1), in that the labeling of said drug failed to bear adequate directions for use, to wit, the directions for use, "Just One Tablet A Day" in the aforementioned leaflet and "In case of pronounced female sex hormone deficiency take 3 tablets daily before meals for 10 days. After the 10-day period take 1 tablet daily or as directed by your physician," borne on the carton label, were not adequate directions for use;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce as aforesaid, was further misbranded within the meaning of 352(f)(2), in that the labeling of said drug failed to bear such adequate warnings against unsafe dosage and duration of administration in such manner and form as are necessary for the protection of users in that each tablet of said drug contained .1 milligram of crystalline alpha estradiol and the labeling of said drug failed to warn that the use of said drug in the dosage and with the duration of administration recommended on its labeling may result in uterine bleeding and damage to the ovaries;

That said drug, when caused to be introduced and delivered for introduction into interstate commerce

as aforesaid, was further misbranded within the meaning of 352(j), in that said drug was dangerous to [378] health when used in the dosage and with the frequency prescribed, recommended and suggested in its labeling since each tablet of said drug contained .1 milligram of crystalline alpha estradiol and the use of a drug containing .1 milligram of crystalline alpha estradiol with the frequency prescribed, recommended and suggested in its labeling, to wit, as directed on the box label, "3 tablets daily before meals for 10 days. After the 10-day period take 1 tablet daily" would be dangerous to health since such use of said drug may result in uterine bleeding and damage to the ovaries.

JAMES M. CARTER,
United States Attorney.

By /s/ ARLINE MARTIN,
Asst. United States Attorney.

[Endorsed]: Filed April 8, 1949. [379]

United States of America in and for the Southern
District of California, Central Division

No. 20596—Criminal

UNITED STATES OF AMERICA,

Plaintiff,

vs.

EL-O-PATHIC PHARMACY, INC., a Corpora-
tion, and MARTIN A. CLEMENS, an Individ-
ual, Manager and Director of Said Corporation,
and MARTIN A. CLEMENS, an Individual,
Trading as M. A. CLEMENS PHARMACY,
Defendants.

Honorable Delbert E. Metzger, Judge presiding

REPORTERS' TRANSCRIPT OF
PROCEEDINGS

Los Angeles, California

June 22, 1949

Appearances:

For the Plaintiff:

JAMES M. CARTER,

United States Attorney; by

GEORGE E. DANIELSON,

Assistant United States Attorney, and

NORMAN W. NEUKOM,

Assistant United States Attorney.

For the Defendants:

CARL B. STURZENACKER, ESQ., and
EUGENE M. ELSON, ESQ.,

1204 Taft Building,
1680 North Vine Street,
Hollywood 28, California. [2*]

The Clerk: No. 20596, United States of America
vs. El-O-Pathic Pharmacy, Inc., and Martin A.
Clemens.

Mr. Danielson: Ready for the government.

Mr. Elson: Ready for the defendants.

The Clerk: Your name is——

Mr. Danielson: George E. Danielson.

The Clerk: Thank you. And your name, sir?

Mr. Elson: Eugene M. Elson.

The Clerk: And is the defendant Martin A.
Clemens present?

Martin A. Clemens: Yes.

Mr. Elson: He is. [3]

* * *

(Counsel for the Government and the De-
fendants then filed a Stipulation as to Facts.)

* * *

Mr. Danielson: Dr. Thienes, please.

CLINTON H. THIENES, M.D.

called as a witness on behalf of the government,
being first duly sworn, testified as follows: [10]

* Page numbering appearing at top of page of original Reporter's
Transcript of Record.

(Testimony of Clinton H. Thienes, M.D.)

Direct Examination

* * *

(Government's Exhibits 1-15 were then admitted in evidence without objection.)

* * *

Q. (By Mr. Danielson): Doctor, will you state your address, please?

A. I live in Los Angeles.

Q. And what is your present occupation?

A. I am Professor of Pharmacology and Toxicology and Head of the Department of Pharmacology and Toxicology in the University of Southern California.

Q. Of what school or schools are you a graduate and with what degrees and the dates, please?

A. I received the Bachelor of Arts Degree from the University of Oregon in 1918. In 1923, I received the Doctor of Medicine Degree and the Master of Arts Degree from the [12] University of Oregon, having completed a course in medicine at the University Medical School.

Mr. Elson: Will you speak a little louder, Doctor?

The Witness: Yes.

And, having done work there, I received the Graduate Degree of Master of Arts during that period, five years.

Q. (By Mr. Danielson): Have you had any post-graduate work, Doctor, other than that described?

A. I did post-graduate work also at Stanford

(Testimony of Clinton H. Thienes, M.D.)

University Medical School. I received the Doctor of Philosophy Degree in 1926 from Stanford University.

Q. And what was your major subject or specialty in getting that degree?

A. Pharmacology and toxicology.

Q. Are you a member of any scientific medical body?

A. Yes; I am a member of the American Society of Pharmacology and Experimental Therapeutics, Incorporated, the International Society known as the Society for Experimental Biology and Medicine, the American Association for Advancement of Science, and a Fellow of the American Medical Association. I am a member of the Los Angeles County Medical Association and the California Medical Association, the Western Society for Clinical Research, and I am an honorary member of the Los Angeles Society of Internal Medicine and the Los Angeles Academy of Medicine. I am a member of the Western [13] Society for Psychosomatic Medicine.

Q. Doctor, are you recognized in any biographical encyclopedia, such as Who's Who?

A. Yes.

Q. What would some of those be, please?

A. I am in Who's Who in America, American Men of Science, Leaders in Education, and a number of other Who's Who, one of them an international Who's Who.

Q. Have you published any books, Doctor?

(Testimony of Clinton H. Thienes, M.D.)

A. I have published a textbook of toxicology, called the Clinical Toxicology, and a textbook of pharmacology, known as Fundamentals of Pharmacology, and a field manual in toxicology for agricultural workers.

Q. Do you know whether any of these books are used in colleges or universities?

A. The first two are used in quite a number of the universities of this country and abroad.

Q. Have you published any other scientific papers, articles or other literature?

A. There is a list of 115 scientific periodicals of which I am either the author or the director of the research and the writing of the paper.

Q. And what subject were you principally interested in in these writings?

A. Pharmacology and toxicology. [14]

Q. Have you in the past, Doctor, engaged in the practice of medicine? A. I have.

Q. For about how long?

A. I have been licensed to practice medicine since 1928 and have practiced as a consultant since then.

Q. You are still practicing as a consultant?

A. I am. And I have had a private office, for private patients, six or seven years. [15]

Q. (By Mr. Danielson): You are a specialist in what field, Doctor, if any?

A. In practice or as a scientist?

Q. As a scientist.

A. Pharmacological and toxicological.

(Testimony of Clinton H. Thienes, M.D.)

Q. What is pharmacology, Doctor?

A. Pharmacology is the science of the nature and action of drugs or medicines.

The Court: I do not recall whether you stated that you are a member of the A.M.A.?

The Witness: I am a fellow of the American Medical Association.

The Court: Have you any connection with naturopathic organizations?

The Witness: No, sir.

Q. (By Mr. Danielson): Does pharmacology include any study of the effects of these drugs that you mention?

A. Which drugs are you referring to, sir?

Q. You have mentioned that pharmacology is a study of the science of drugs and toxic effects.

A. And nature and actions to the uses, I should have said, therapeutic uses.

Q. Would that be as to humans as well as animals?

A. Yes, certainly.

Q. Well, does it include a study of the toxic or dangerous [16] effects as well as these drugs?

A. It does.

Q. Are you familiar with the male sex hormones, Doctor?

A. Yes.

Q. Is one of these hormones commonly designated as testosterone?

A. It is.

Q. Do you know whether the body of the normal male adult generates testosterone?

A. Yes, it does.

(Testimony of Clinton H. Thienes, M.D.)

Q. In what form? A. As testosterone.

Q. Just pure testosterone, is that correct?

A. Yes.

Q. And that is generated by what organ or organs? A. The testes.

Q. Is that a gland, Doctor?

A. Yes, it is a gland.

Q. Does the body of the male adult always provide an adequate supply of testosterone?

A. No.

Q. In such event of a deficiency, can it be supplied to an individual? A. Yes, it can be. [17]

Q. Now, in what form, Doctor?

A. Well, as testosterone or as testosterone propionate or acetate or as methyl testosterone. These are the principal forms in which it is used.

Q. Doctor, would you speak a little louder, please, and would you explain how these forms are actually different from pure testosterone, particularly methyl testosterone?

A. The difference between testosterone and methyl testosterone is that there is an extra atom of carbon and three extra atoms of hydrogen in the molecule, the one atom of carbon and three of hydrogen being joined together in the form of the methyl radical, CH₃ radical, which is attached to one of the carbon atoms of the testosterone.

Q. What is the practical effect of that difference from pure testosterone?

A. The methyl radical makes the compound more readily absorbed from the digestive tract.

(Testimony of Clinton H. Thienes, M.D.)

Q. Now, again, in the event of a deficiency of testosterone in the males, can this deficiency be supplied to a human?

A. You mean the method of administration?

Q. That is correct, the routing I mean.

A. Methyl testosterone may be supplied in tablets, to be swallowed, or in small tablets often known as linguets to be placed under the tongue and allowed to slowly dissolve and [18] be absorbed by the mucuous membrane under the tongue.

Testosterone must be injected, although it is given by mouth, but its absorption from the digestive tract is poor. So that usually it is injected, either in solution, in an oil, or as crystals suspended in water or saline or glucose, or as pellets which are implanted under the skin or into a muscle surgically.

Testosterone dipropionate is usually dissolved in an oil and injected.

Q. Doctor, what, if any, difference is there in the effect of administering testosterone in these different forms or by different routes?

A. No difference. They all have the same effect.

Q. And what is that effect, that is, the effect of what?

A. The effect of testosterone.

Q. Are you familiar, Doctor, with the female sex hormones?

A. Yes.

Q. What are they called, generically?

A. There are two classifications. One class are the estrogens and the other might be called the progestational hormone.

Q. What is the meaning the the term estrogens?

(Testimony of Clinton H. Thienes, M.D.)

A. They are the hormones which are compounds which [19] cause estrus (e-s-t-r-u-s) and there are other spellings as well, in animals and in human and produce analogous effects such as increase in the size and number of cells in the uterus and mammary gland.

Q. Does the body of the normal female adult human generate estrogens? A. It does.

Q. In what form?

A. Principally estradiol or alpha estradiol.

Q. And what gland or glands generate this?

A. The ovary, principally.

Q. Does the body of the normal female human adult always generate an adequate supply?

A. No, it does not.

Q. Can these estrogens be supplied to a woman who is deficient in her own natural supply?

A. It can.

Q. In what ways can it be supplied?

A. Either in oral solution, the alpha estradiol or estrone or similar compounds, which are products of metabolism of the estradiol and have the same type of effect; they may be dissolved in oil and injected; they may be combined with certain radicals such as the benzoate estradiol, propionate or dipropionate and dissolved in oil and injected, or they may be given by mouth; and certain radicals attached to [20] estradiol will make it more easily absorbed, just as in the case of testosterone, and then the crystals may be suspended in water and

(Testimony of Clinton H. Thienes, M.D.)

injected or made into pellets and surgically implanted under the skin or into the muscle.

The Court: What is propionate?

The Witness: Propionate, that is an acid radical, an organic acid containing three carbon atoms, which combines—which can be made to combine with estradiol, alpha estradiol, to form a more complex compound which is more slowly disintegrated in the body and therefore acts longer than the alpha estradiol.

The Court: Is that the purpose of the combination?

The Witness: In the case of alpha estradiol dipropionate it is to give a more prolonged action.

The Court: Can the estrogens be supplied by rubbing on the skin, Doctor?

A. Yes, they may be dissolved in fatty materials or in fat solvents and applied to the skin.

Q. Does the normal female human adult continue to have a source of natural supply, a natural source of supply of estrogens throughout her life?

A. At the period we call the menopause or the change of life, the secretion of the natural estrogens is reduced to a very small amount and may be entirely stopped.

Q. Now, you have described the various, different forms [21] of estrogens in the female hormone and the various, different manners of administration. Is there any difference in the effect by administering it in these different manners or in the different forms?

A. No.

(Testimony of Clinton H. Thienes, M.D.)

The Court: Is there, as to the efficiency?

A. Well, that is a matter of dosage and efficiency of absorption, of course. For instance, when rubbed on the skin, the amount that gets into circulation for a given weight of the compound applied would be usually less than that which would get into circulation from injection.

Q. (By Mr. Danielson): Now, Doctor, you testified that the generic term for one class of the female sex hormone is estrogens. Are there other estrogens besides alpha estradiol?

A. Yes, there is estrone, which is secreted into the urine of humans and many animals, also known as theelin, which is widely used. It is less potent but, by giving a large dose, the same results are obtained as with estradiol, and then there is a similar compound excreted into the urine and known as estriol or theelol. Then, there are others, still, especially which are found in the urine of horses, known as equilin and equilenin. These are of minor importance, medically.

Q. Are all these natural estrogens, Doctor? [22]

A. Yes. All that I have named are natural estrogens.

Q. Are the effects of all natural estrogens the same?

A. As far as the effect upon the uterus and the breasts and the skin, yes.

Q. Now, Doctor, in your profession as pharmacologist, are you familiar with the United States

(Testimony of Clinton H. Thienes, M.D.)

Pharmacopoeia, Official National Formulary and the Official Homeopathic Pharmacopoeia of the United States? A. I am.

Q. Have you examined these publications to ascertain whether they mention the drug alpha estradiol?

A. The United States Pharmacopoeia lists it.

Q. And by what name is this drug designated in the United States Pharmacopoeia?

A. As estradiol and as alpha estradiol.

Q. Is this drug also designated in the United States Pharmacopoeia by the name Female?

A. No.

Q. Have you examined the three compendia which I have named to determine whether there is any drug listed under the name Female?

A. I have, and I have found no such drug.

Q. What is the common or usual name of alpha estradiol?

A. It is either alpha estradiol or estradiol.

Q. Is it ever referred to commonly or usually as female? [23] A. No.

Q. Now, Doctor, on the basis of your education, your professional training and experience, your study of the scientific literature, medical literature, your participation in conferences and discussions with other doctors and other scientists and your research and clinical experience, do you know the consensus of medical opinion regarding the toxic effects which methyl testosterone may have upon the adult male? [24] A. Yes, I think I do.

(Testimony of Clinton H. Thienes, M.D.)

Q. What is that consensus of medical opinion?

Mr. Elson: I object to that, on the ground that it calls for a conclusion of the witness and there is no foundation laid. It may be true that the doctor has had considerable experience in reading and in conferences and so on, but we still don't know what the consensus of medical opinion is and how far-reaching it is necessary to go in order to determine it. It might be the consensus of opinion in this locality, but, what would be a consensus of opinion here would not necessarily be the consensus of opinion nationally or internationally or in some other locality.

Mr. Danielson: If your Honor please, the defendants' objection I believe is as to the weight or credibility of this doctor, of this witness' opinion, rather than as to whether or not it should be admissible. Similar points have been raised before, and there is precedent within the Ninth Circuit as to the admissibility of a qualified witness' opinion as to the consensus of medical opinion. In the case of *Research Laboratories vs. The United States*, decided in April, 1948, by the Ninth Circuit Court, reported in 167 F(2d) 410——

The Court: Yes. Well, upon the doctor's qualifications, I think that his opinion on that subject should be admitted, subject, of course, to cross-examination as to how far it may reach or what its limits may be. I overrule the objection. [25]

(Testimony of Clinton H. Thienes, M.D.)

A. The methyl testosterone may produce a condition which is known as oligospermic, or even aspermia. These conditions are characterized by deficiency or absence of spermatozoa formation or liberation, and also it has been known to exaggerate or hasten the development of carcinoma, cancer of the prostate gland in males.

Q. Doctor, what do you mean by oligospermia, please?

A. Deficiency in the number of sperm or spermatozoa which are liberated by the male.

Q. What does that mean, in ordinary language?

A. Well, it would mean a deficiency in the ability to reproduce.

Q. And what is the meaning of aspermia, Doctor?

A. Absence of sperm.

Q. Now, you have stated what is the consensus of medical opinion. Is that your own opinion, also based upon the same background?

A. Yes.

Q. Would you explain what you mean by carcinoma of the prostate, how would you define that?

A. Well, another term is cancer of the prostate. The [26] prostate gland is a gland in the male which is one of the secondary reproductive glands. It secretes a fluid for carrying the sperm and it contains epithelial cells which are the secretory cells. Now, some of these epithelial cells, new cells of the type we call malignant or cancerous may develop; and in the early carcinoma or early cancer, the presence of the cancerous growth may not be recognized. It often occurs in middle age, at about the

(Testimony of Clinton H. Thienes, M.D.)

time that the sex hormone may decrease in the amount of production and testosterone might be given to relieve the symptoms which the individual feels as a result of deficient secretion of testosterone and the administration, then, of the methyl testosterone would stimulate the cancerous growth and perhaps carry it to the point where it is no longer curable.

Mr. Elson: I did not hear the last.

The Witness: Well, the cancerous growth might develop under the influence of methyl testosterone to the point where it is no longer curable.

Q. (By The Court): Now, normally, the human system, through what, the glands, supplies some testosterone? A. Yes.

Q. And that may diminish with physical conditions or age?

A. Yes, or infections, or a number of other things.

Q. And to attempt to supply that, you say creates a [27] danger?

A. Yes, there is a danger, and if the patient is not being carefully observed, the cancer would develop beyond the point of curability. In other words, a physician supplying testosterone or methyl testosterone, or any of its forms, is aware of this danger and therefore he examines the patient at frequent intervals, to see that there is no tumor developing in the prostate gland.

Q. (By The Court): Well, is there any condition you know of where the system may create an

(Testimony of Clinton H. Thienes, M.D.)

oversupply of that, without being aided by testosterone?

A. By the administration of it, you mean?

Q. Yes. The reason the thought occurs to me is that it is generally known that there are many cases of cancer of the prostate gland? A. Yes.

Q. (By The Court): And I was just wondering why that gland seems to be quite susceptible to a cancerous growth.

A. I don't think that we can answer that question, sir. We don't know yet why a given gland is more susceptible to a given type of cancer. We just know of this relationship. We know that in cancer of the prostate, that castration will aid in the cure or at least diminish the rate of development of the cancer of the prostate and of course castration removes the source of the secretion of natural testosterone. [28]

Q. (By The Court): Would the diminution in the supply of testosterone have any effect toward promoting a cancerous condition?

A. Not in the prostate.

Q. (By The Court): It would not?

A. It would inhibit the development of the cancer in the prostate, when the testosterone secretion is diminished.

Q. (By The Court): Would changes of habits in life or dietary or other conditions of that sort tend to enlarge or increase the amount supplied by the human system?

A. Well, a defective diet, starvation or malnutri-

(Testimony of Clinton H. Thienes, M.D.)

tion will decrease the function of the testes and therefore would decrease the secretion. That is the only situation in which I think diet would influence it. A defective diet will definitely decrease the activity in the size of the testes. As far as other conditions in life are concerned, I don't think we have enough information to answer that question.

The Court: All right. Well, I trust that neither you, Doctor, or counsel consider the court as cross-examining the witness.

Mr. Neukom: No, no.

The Court: These thoughts occurred to me. I would like to have a little more expansion and it is for the betterment of my understanding that I am asking these questions as we go along. Proceed. [29]

Q. (By Mr. Danielson): In view of what you have just testified, Doctor, would the acceleration of a prostatic cancer be dangerous? A. Oh, yes.

Q. And why? What are your reasons for that?

A. Rapidly growing cancers will tend to disseminate through the lymphatic channels of the body to other parts of the body. A cancer is a serious thing, because cells or portions of the tumor break off into the lymph and blood channels and are carried to other parts of the body where they develop and often cannot be reached surgically. If a cancerous growth was limited to the point of origin, that is, if a prostatic cancer in this case remained in the area of the prostate, it could be removed surgically. But the danger of cancer is, and especially of the rapidly developing ones, that

(Testimony of Clinton H. Thienes, M.D.)

cancerous cells break off from the original growth and migrate into other parts of the body, particularly through channels, particularly the lymph channels, and locate in bones and the brain and various parts of the body where often they cannot be removed.

Q. Doctor, a while back, when I was asking you questions relative to the various compendia, the pharmacopeia, I see that I failed to ask you whether alpha estradiol was designated in either of the National Formulary or the Homeopathic Pharmacopoeia of the United States. [30]

A. No. They are not in either of those.

Mr. Danielson: Counsel, will you stipulate that those three are the three——

Counsel will stipulate, your Honor, that the United States Pharmacopoeia, the National Formulary and the official Homeopathic Pharmacopoeia of the United States are the official compendia. That is correct, is it not, Mr. Elson?

Mr. Elson: Yes.

Q. (By Mr. Danielson): Doctor, on the basis of your education, your professional training, experience, your studies of these medical and scientific literature, conferences, discussions with other doctors and scientists and your clinical laboratory experience, do you know the consensus of medical opinion regarding the toxic effects which alpha estradiol may have upon the adult female?

A. Yes.

(Testimony of Clinton H. Thienes, M.D.)

Q. And what is that consensus of medical opinion?

A. In line with the testimony I have just given about the male hormone, it is that it also accelerates cancerous growth, particularly in the female breast, also in the male breast as far as that is concerned; long-continued administration also leads to tumors particularly of the uterus and may interfere with the normal menstrual cycle.

Q. (By Mr. Danielson): It is likewise your opinion based upon the same background? [31]

A. Yes.

Mr. Danielson: You may cross-examine. [32]

* * *

Cross-Examination

By Mr. Elson:

Q. Doctor, we are concerned in this case, so far as carcinoma of the prostate, with its early and incipient stages. That is the language that is employed in the information. Can you diagnose the presence of carcinoma of the prostate in an individual in its incipient stages?

A. As a rule, not.

Q. Isn't it also true that, when you are able to diagnose [33] carcinoma of the prostate in an individual, it is no longer incipient?

A. I suppose that is a matter of definition but, in general, I would say that is true, except for this, if I may say it. In case the prostate is large and

(Testimony of Clinton H. Thienes, M.D.)

is removed, then, of course, the carcinomous process can be identified by the pathologist.

Q. But, until it is removed, it is quite difficult to determine it in every case, isn't it?

A. Yes.

Q. Your methods of diagnosing that condition are by palpation and biopsy, are they not?

A. In general, that is true.

Q. In other words, a biopsy is going in and taking a specimen of the material, is it not?

A. That is right.

Q. And then, in the case where you suspect that there might be a carcinoma of the prostate, you don't remove the prostate but you perform a biopsy and take a specimen of the material, and it might well be that the specimen you take is not part of the affected area, isn't that true?

A. If biopsy is done; yes.

Q. And isn't it also true that there can be a carcinoma of the prostate that will have with it a benign hypertrophy?

A. Yes. [34]

Q. Cancer of the prostate in an individual, after it has passed its incipient stage, is usually associated with manifestations that the patient feels in some way, are they not, or is it not?

A. Not necessarily.

Q. What are the manifestations that the ordinary person feels because of a prostatic cancer?

A. Usually difficulty in urination because of the pressure of the enlargement upon the urethra, the urinary tract.

(Testimony of Clinton H. Thienes, M.D.)

Q. Anything else?

A. We are talking about the early form, are we?

Q. No. I am talking about it after it has passed its incipient stage.

A. If it has got to the point where it is metasticized, there would be symptoms from other organs into which the cancerous cells have scattered and begun to grow.

Q. And hasn't it been your experience that a person whose condition is affected by a prostatic cancer that has passed the incipient stage and is diagnosable comes to a doctor for relief, not knowing what it may be, but for relief anyway?

A. Yes.

Q. And the doctor examines him to determine whether he has a prostatic cancer, and, if he finds one, I take it that [35] one of the things he advises him is not to take any testosterone?

A. That is true.

Q. The urologist is usually the one who does this prostatic examination for a cancer, doesn't he?

A. No; I don't know that.

Q. Isn't it usual, if a man goes to his own physician, who is simply an internist, and the doctor suspects that the man may have cancer of the prostate, he sends him to a urologist to make that examination?

A. If he goes to an internist, he is sent to an urologist.

Q. And, if he goes there first to the urologist, he is there anyway?

A. That is right.

(Testimony of Clinton H. Thienes, M.D.)

Q. Isn't it your experience and isn't it your opinion that, if a man went to an urologist, and prostatic cancer was advised, the urologist would, of course, so advise his own doctor, and that his own doctor then would advise him not to take any testosterone and would not prescribe it for him, if he otherwise showed symptoms in which it was ordinarily used?

A. You put several things together. I would say "Yes" to some and "No" to others. I think it should be divided up so I can answer each part.

Q. Would you tell us, then, what you mean by "Yes" and what you mean by "No" and as to which parts of my compound question?

Mr. Danielson: Could the question be read back? It is rather confusing.

Mr. Elson: Surely.

The Court: Yes.

(Question read by reporter.)

Q. (By Mr. Elson): Do you understand the question? A. I think so.

Q. If you don't, I don't want you to be confused. I will put it in another way and see if I can straighten it out. Let's take a hypothetical example of a man who goes to see his own doctor and, from the history of the patient, the doctor suspects that probably or possibly he might have a cancer of the prostate. Let's assume that the doctor sends him then to an urologist for such examination and the urologist, after examining him, concludes that he

(Testimony of Clinton H. Thienes, M.D.)

does have a cancer of the prostate and so advises the man's doctor. Let's assume that the man goes then back to his doctor and that he is manifesting symptoms of the climacteric. Isn't it true that his own doctor under those circumstances would not prescribe testosterone for him and would advise against the use of it by him? A. Yes. [37]

Q. If that same man had gone to the urologist and he had an incipient carcinoma of the prostate, which the urologist was unable to discover either by palpation or by biopsy, and the urologist so advised the man's own doctor, and that same man had symptoms of male climacteric, is it your opinion that ordinarily such a doctor would prescribe testosterone propionate for him and maybe later methyl testosterone?

A. In many instances, I think the physician probably would prescribe one of the testosterone preparations. I am assuming, of course, that the symptomatology is adequate for the diagnosis of male climacteric, which is a very unusual diagnosis.

Q. I assumed that in my question also.

* * *

The Witness: Perhaps I should say it is a very unusual correct diagnosis.

Q. (By Mr. Elson): Do you mean that it is unusual for a doctor to correctly diagnose whether a man is going through the male climacteric?

A. What I mean is that male climacteric is a very unusual condition and that this hypothetical

(Testimony of Clinton H. Thienes, M.D.)

situation which you [38] describe would be a very unusual one.

Q. Whether you call it the male climacteric or not, let us take an individual who has flushes, sweats, extremely nervous, inability to concentrate, nocturia. Let's say that he is a man around 50 years old or so. I don't mean to be all inclusive in the symptoms that I have just related. But isn't it your opinion that the average general practitioner, other things being equal, would under those circumstances prescribe testosterone for a period of time and wait and see whether the symptoms were relieved?

* * *

The Witness: I think we would have to know more of what the general practitioner's examination had consisted in and what the report—or what the urologist may have done in the way of examination, to answer that question.

Q. (By Mr. Elson): Let's assume that the urologist's report was that he had palpated the prostate and performed a biopsy and there was no evidence of cancer of the prostate.

A. And no enlargement of the prostate? [39]

Q. No. A. What about laboratory tests?

Q. Of what?

A. Oh, excretion of hormones.

Q. All right. Let's include that, that there was a laboratory test conducted.

A. With what results?

Q. What? A. With what results?

(Testimony of Clinton H. Thienes, M.D.)

Q. Negative.

A. I don't know what you mean by "negative" there.

Q. Well, with nothing to indicate as a result of that laboratory test that there was any presence of cancer of the prostate.

A. But that wouldn't be adequate.

Q. What would be adequate?

A. You would have to have proof that there was a marked decrease in the secretion of testosterone.

Q. Is it your opinion that such a complete examination is made in every case that an individual is sent to an urologist?

A. Well, I would say it would depend on what the urologist was asked but I think also that most competent urologists would insist upon—or, first of all, he would return the patient with advice to the physician and, before [40] arriving at a conclusion as to what advice he would have to give, he would certainly determine whether or not there was evidence of male climacteric and that would involve determination of the secretion of male hormone.

Q. You are bringing that last into the picture for this reason, to see whether or not there was a deficiency of male hormone in the individual?

A. Yes.

Q. I think we can agree, can't we, that a male hormone product will not benefit a person who is not suffering from a deficiency of male hormone?

A. That is right.

Q. And so it would only be then, if a man was

(Testimony of Clinton H. Thienes, M.D.)

actually suffering from a deficiency of the male hormone, and the urologist's diagnosis had been that he found no evidence of carcinoma of the prostate, that the general practitioner would prescribe testosterone for him?

A. Are you assuming these laboratory tests I have talked about, too?

Q. Yes.

A. Then, I think the doctor would give testosterone in one of its forms.

Q. Let's assume, say, that the urologist didn't conduct a laboratory test. Doesn't it often happen that the general practitioner will, after receiving a negative report [41] on prostatic cancer from the urologist, prescribe testosterone for the man for a certain period of time, to see whether or not any relief accompanies the administration of it?

A. No. I think today the general practitioner would want to know for sure whether this was a case of climacteric or not before he would give the testosterone.

Q. Is it your opinion that the average general practitioner will require a laboratory test before prescribing testosterone for a patient who is complaining of symptoms which seem to be associated with male climacteric?

A. I don't know what you mean by the average general practitioner.

Q. Just that.

A. There ain't none. There is no such animal.

Q. There is no average doctor? A. No.

Q. Well, would you say that the majority of doc-

(Testimony of Clinton H. Thienes, M.D.)

tors, general practitioners, would require a laboratory test prior to a prescription of that?

A. I think today they would.

Q. Is that simply your thought or just what is it based on?

A. It is based upon knowledge of medical literature largely, and the literature today is such that most doctors are aware of the danger of symptoms and prostatic cancer, by [42] giving testosterone preparations, and therefore they are very cautious about it.

Q. I now go to another phase. Can you say as a fact that it has ever been demonstrated by clinical tests that testosterone was responsible for a prostatic cancer?

A. The testosterone has been responsible for prostatic cancers growing rapidly, whatever they were diagnosed. I would not say that testosterone will cause a cancer to develop. I mean by the word "develop" to be actually started, and the cells which become cancer cells to be produced from normal epithelium near the prostate, but, once the cancer is started, then the testosterone has been known to exaggerate it.

Q. By clinical proof it has been known to exaggerate it? A. Yes.

Q. Or is that simply an assumption or an inference, rather, from other things? Can you give me any example in which it was clinically proven that testosterone accelerated the growth of a prostate cancer?

(Testimony of Clinton H. Thienes, M.D.)

A. I don't remember any specific instance at the moment.

Q. You are familiar with at least some of the literature that has discussed the subject, are you not? A. Yes. [43]

Q. And isn't it a fact that that literature simply says to this effect, in substance, that testosterone may cause the acceleration and the growth of a prostatic cancer; that it has been suggested that it may cause the acceleration and so on; and that in none of the literature has any investigator reported that he was able to prove medically that it did so?

A. That isn't my interpretation of the literature.

Q. Can you tell me, Doctor, what literature you have reference to that leads you to that interpretation?

A. I can't point to any specific article at the moment. There are a number of papers of a man named Huggins particularly that I recall, that have shown the effect of testosterone upon prostatic cancer. [44]

Q. (By Mr. Elson): And Huggins, as I understand it, and you may correct me if I am wrong, was one of the few investigators who did any amount of work on that subject? A. That is right.

Q. And is there anything, in any of the reports of Huggins, as you recall it, in which he reported that a carcinoma of the prostate had been clinically proven by him to have been accelerated by the administration of testosterone?

A. I don't recall that.

(Testimony of Clinton H. Thienes, M.D.)

Q. As a matter of fact, isn't your recollection that Huggins reported that because of his experience in castrating some 20 males and watching the results following that castration, that he was of the opinion that testosterone may accelerate the growth of a prostatic cancer?

Mr. Danielson: I would like to interpolate one question, your Honor: To which Huggins or what Huggins is counsel referring?

Mr. Elson: I think there is only one, isn't there?

The Court: I assumed that they were in agreement, as between counsel and the witness, as to Huggins. I don't know him.

Mr. Danielson: For the sake of the record, I would like to have it shown what Huggins he is referring to.

The Court: Very good. [45]

Q. (By Mr. Elson): Do you know of any other Dr. Huggins, Dr. Thienes, who is mention reputably in the literature with regard to experiments having to do with prostatic cancer?

A. I do not. The one I am referring to is now Professor of Surgery at the University of Chicago.

Mr. Danielson: If your Honor please, we intend to bring Dr Huggins to the witness stand in this particular case, at a later time.

The Court: Let us connect that up, with the time that Dr. Huggins reported.

Q. (By Mr. Elson): Do you remember when he wrote or rendered his report?

A. He is still reporting, but the earliest reports

(Testimony of Clinton H. Thienes, M.D.)

are several years ago. I would hesitate to say the particular number of years.

Q. To refresh your memory, was it in 1939?

A. I would hesitate to say.

Q. By the way, while I am trying to find something here, you have stated what your interpretation of the consensus of medical opinion is, or the effect that methyl testosterone may have on sterility, in causing sterility, and also that alpha estradiol accelerates cancer of the breast, cervix and uterus, am I correct?

A. Yes. [46]

Q. Well now, in arriving at what you understand to be the concensus of medical opinion, you take into consideration the reports, writings and investigations of others, do you not?

A. That is right.

Q. And those reports, investigations and so on are found not only in medical books, but they are found in The Journal of the American Medical Association, the Urologic and Cutaneous Review, the Journal of Clinical Endocrinology and others, am I correct?

A. Yes.

Q. And based upon what you read as reported by others in those, in that literature and other comparable publications, coupled with your own experience and your study generally, you then arrive at what you believe to be the concensus of opinion on this, that or the other subject, am I correct?

A. Yes.

Q. And that is true, isn't it, with all doctors that you know of?

A. Yes, I think so.

(Testimony of Clinton H. Thienes, M.D.)

Q. Isn't it also true that other doctors, and let us say all of them, with the qualification that they are competent, intelligent, interested men in their profession, keep abreast of what to do and what not to do with respect to their [47] patients, by experiences in their own practice plus the reports of others such as I have mentioned?

A. Yes, that is true.

Q. And that, with that experience and also taking into consideration the reports of others, they will with their patients try out on them, all things being equal, the method of administration or whatever it might be as reported successfully by one of these other investigators?

A. That is often true.

Mr. Elson: Well now, if the court will bear with me here a moment.

Q. Oh, by the way, in the literature that you have read which discusses the use of testosterone, is it your recollection that in practically all of those articles the writer warns against the use of testosterone when cancer of the prostate may be indicated?

A. Yes.

Q. You are sure of that?

A. Most of the current writings, yes.

Q. Now, I think you stated, Doctor, that in the case of prostatic enlargement, a suspicion would arise in your mind whether or not a carcinoma was present?

A. Yes.

Q. Do you know of a doctor by the name of Walter M. Kearns of Milwaukee? [48]

(Testimony of Clinton H. Thienes, M.D.)

A. No, I don't know him.

Q. You have never heard of him?

A. I may have heard of him. I don't recall his name at the moment.

Q. Are you familiar with the name of a doctor by the name of Harry Benjamin, who wrote at least one article for the Urologic and Cutaneous Review in 1946?

A. I don't remember it.

Q. The subject of his article was A Contribution to the Endocrine Aspect of the Impotence Problem, a Report of 39 Cases. His name is Dr. Harry Benjamin, M.D., New York City. That appeared in the Urologic and Cutaneous Review, Volume 50, March, 1946, page 143, and I am going to state to you what he stated on that page; under his title of Summary Conclusions and General Remarks: "Since large amounts of the hormone may suppress gratuitous function temporarily and thus aggravate the sexual inadequacy or may stimulate growth of dormant cancer cells in the prostate, doses not higher than 10 milligrams testosterone propionate twice or three times a week seem advisable."

Now, coming back to your previous statement, you stated, I believe, that you had no recollection of any investigators reporting that it was only the testosterone which might accelerate cancer growth, and that there had been no reported case of—that you did not know of any such qualification, [49] that I bring that to your attention and ask you, after my having read that to you, is your opinion as previously expressed in any wise altered?

A. No.

(Testimony of Clinton H. Thienes, M.D.)

Q. In other words, you don't agree with it?

A. I don't agree with your interpretation of what he says.

Q. Well, Doctor, I read it. You can read it, if you wish. I read it right out of the article.

A. Well, you are inferring——

Mr. Danielson: I object to this as argumentative. The doctor has stated his opinion and his reasons therefor.

Mr. Elson: Well, I am willing to let it stand as it is. [50]

* * *

The Court: Well, that will be all right. Just before we do adjourn, I would like to get a few little wrinkles straightened out. You must know that a great deal of this technical matter is new to the court, I mean the medical and the clinical matter.

May I ask you, Doctor, your testimony, as I get it, is that any case of enlargement of the prostate gland is a suspicious thing with relations to cancerous possibility? [51]

A. Yes.

Q. Or even probability?

A. Well, there is a certain probability.

Q. The practice, then, I believe that of so many physicians is to undertake to alleviate the enlargement, reduce it by some form of massage or some similar treatment?

A. Well, only under certain special circumstances would massage be used. Where the prostate

(Testimony of Clinton H. Thienes, M.D.)

is large enough to produce serious symptoms, usually operation is advised.

Q. Massage would be detrimental if there was a cancerous condition? A. That is right.

Q. Now, tell me again (I think you have gone over this), if you can very briefly: How has it been determined that testosterone promotes the growth of cancer cells in the prostate and in the breast?

A. Well, testosterone does not promote cancerous growth in the breast. That is the action of the extrogens that does that——

Q. Oh, yes.

A. ——but, there are various types of evidence to support the conception that testosterone stimulates cancer of the prostate, it hurries its development; for instance, from a statistical point of view, the profession interested in this field are aware of the rate, the usual rate of development of [52] cancer of the prostate. Whenever testosterone administration has been associated with prostatic cancer, it has been shown that the development has been much more rapid than would be anticipated from knowledge of the development of the prostate when testosterone is not administered, for instance.

The Court: Well, that has been the index?

A. That is the one that comes to my mind at the moment, yes. There are other criteria which I assume other witnesses will enlarge upon. [53]

(Testimony of Clinton H. Thienes, M.D.)

Q. (By Mr. Elson): Doctor, I think you testified on direct examination that the concensus of opinion was that methyl testosterone would cause sterility? A. Yes.

Q. Now, would the amount of dosage have anything to do with whether or not sterility would be caused?

A. Sterility has been caused by the usual doses.

Q. Meaning what?

A. Oh, 10 to 25 milligrams repeated.

Q. How often?

A. Daily or less frequently.

Q. Now, in arriving at that concensus of opinion as you interpret it, I take it that you, among other things, consulted and have consulted the writings and reports of other investigators appearing in one or more of the publications that I mentioned this morning? A. Yes.

Q. In arriving at that concensus, did you give any consideration [54] to an article appearing by Laurance W. Kinsell, in the Journal of Clinical Endocrinology, December, 1947, entitled "Spermatogenesis in a Pan-hypopituitary Eunuchoid, as the Result of Testosterone Therapy"? Did you?

A. No; I don't remember that article.

Q. Now, if I told you that in that article that investigator reported as follows: "We wish, at this time, to report testosterone-induced spermatogenesis in a 25-year-old male showing both laboratory and clinical evidence of pan-hypopituitarism, using the term in a very broad sense," would that report of

(Testimony of Clinton H. Thienes, M.D.)

that investigator influence you at all in your opinion?

A. Not at all. That is quite a different situation.

Q. I referred this morning in asking a question in connection with your arriving at the consensus of opinion to an article by Dr. Walter M. Kearns in the Wisconsin Medical Journal, entitled "Testosterone." Or did I? Was that one of them? Whether it was or not, let me put it this way. In arriving at your interpretation of that consensus, did you give any consideration to or read the article entitled "Testosterone in the Treatment of Testicular Deficiency and Prostatic Enlargement," by Walter M. Kearns, M.D., Milwaukee, appearing in Volume 40 of the Wisconsin Medical Journal, October, 1941, at page 928, which read as follows:

"Clinical reports indicate equally amazing results when the order is reversed and estrogens are given to the male. Charney has recently brought about correction of abnormal libido in a male sexual criminal by the administration of large doses of stilboestrol, the synthetic estrogen"—well, I don't know what that word means. "There also occurred a cessation of spermatogenesis, with degeneration of the germinal epithelium as proved by testicular biopsy. In this instance testosterone might have accomplished the same result, as depression of spermatogenesis has frequently been demonstrated after the administration of huge doses of testosterone to normal persons"? [56]

After that article has been read to you, does that

(Testimony of Clinton H. Thienes, M.D.)

in any wise alter your opinion to the effect that, as I understand you to say, in most cases the normal dose of 10 milligrams, maybe one or two tablets per day, of testosterone will cause sterility?

A. I don't think I said it that way.

Q. I didn't mean to misquote you.

The Court: 10 to 25 milligrams.

Q. (By Mr. Elson): All right; 10 to 25 milligrams. A. Let me read that. May I?

Mr. Danielson: What page are you reading from?

Mr. Elson: It is on page 928.

A. This does not alter my opinion. His statement that huge doses produce it in normal persons is not contradictory to what I said.

Q. (By Mr. Elson): In other words, you believe——

A. I believe that the ordinary doses also have been known to do the same thing.

The Court: While you are dealing with that, make it a little more comprehensive to a layman, will you? I get the sense of it not too clearly.

Mr. Elson: Your Honor, I will be very frank about it. What I am driving at is this: The doctor has testified that it was his interpretation of the concensus of opinion that testosterone in normal doses say of 10 to 25 milligrams [57] per day would cause sterility in the persons who took it.

The Court: Did you make that conditional?

Mr. Elson: I didn't understand it to be so.

The Court: Do you mean that was just a flat statement?

(Testimony of Clinton H. Thienes, M.D.)

The Witness: I don't mean it would happen to everybody but it does produce sterility in a large number of individuals to make it a dangerous thing if testosterone is given without careful control of the patient.

Mr. Elson: For the purpose of the record, I move to strike the portion of the witness' statement that it would make it dangerous and so on. That is a conclusion for the court to determine at the end of this case.

The Court: He is giving nothing more than his opinion, as I take it.

Mr. Elson: What I am proposing to show here is that as a part of that consensus as he has stated are the writings and the investigations of others, such as these doctors whose articles I have referred to, and that in the articles that I have called to his attention and those which I propose to call to his attention I propose to show that what he says is not a fact necessarily, and that in many cases of spermatogenesis or, in other words, an increase in fertility in the individual is accomplished by the administration of testosterone.

The Court: Very good, but as I understand it, the witness' [58] testimony is that from his observation and experience, discussion and reading, he has formed one opinion. Now you are testing him as to an opinion expressed by others and asking him if that has any tendency to change his view. Thus far, he has answered no. You may go ahead. [59]

Q. (By Mr. Elson): Now, Doctor, what do you mean by sterility?

(Testimony of Clinton H. Thienes, M.D.)

A. Inability to reproduce.

Q. Now, do you mean by your testimony that testosterone will cause sterility, am I correct, in a majority of persons or a large number?

A. A fairly large number, yes.

Q. That that sterility is going to be permanent, even though the person discontinues or the doctor quits prescribing testosterone?

A. No, not necessarily.

Q. As a matter of fact, it is only a temporary condition, is it not?

A. In many cases, yes.

Q. And isn't it true that from either your experience or your reading, that in many cases, spermatogenesis, or fertility has been increased in the individual to whom testosterone has been administered and prescribed?

A. In certain special endocrine disturbances, yes, such as you describe there, which was one of the unusual types of endocrine disease.

Q. Now, when a person goes to a doctor and the doctor prescribes testosterone to him, I take it that the doctor knows that it may cause temporary sterility or a decrease in the sperm count? [60]

A. Yes.

Q. Well, then, the effect is the same, isn't it, whether a doctor prescribes it or whether the person tries it without prescription?

A. No.

Q. Why not?

A. Because the doctor will know when it is safe to continue or discontinue, when it is proper

(Testimony of Clinton H. Thienes, M.D.)

to direct or to discontinue, but the individual who does not have medical advice doesn't know.

Q. Well, as a matter of fact, the ordinary person who would be taking the testosterone is a person in his middle age, isn't it?

A. I presume so, yes.

Q. And do you think that sterility with a person 45 or 50 or 55 or 60 years old is an important factor?

A. Yes, sir.

Q. In what way?

A. I think any man would be willing to answer that. One thing it would have a very bad psychological effect upon an individual.

Q. Well, isn't it a case of being willing to accept the benefits of a product such as testosterone and giving up fertility at least for the time being?

A. Yes, but I don't think a person not medically trained knows when it is safe to make that decision, and there are many other circumstances that have to be taken into consideration.

Q. In your opinion, would a doctor who was prescribing testosterone for a person and who found that it was causing him to be sterile, but who also found when he took him off of testosterone, the same bothering symptoms would return, generally quit prescribing testosterone?

A. Well, the proper indication for testosterone would in a large number of cases be associated with at least a relative sterility.

When testosterone is properly given, sterility or

(Testimony of Clinton H. Thienes, M.D.)

temporary or at least a degree of sterility is often present.

The person who diagnoses his own condition as something requiring testosterone, the chances are that he will not be the type of person that needs it. Therefore, he would not be, ordinarily, sterile and he would produce sterility in himself, which is quite a different circumstance from the type of patient that the doctor is going to treat.

Q. A moment ago you spoke about testosterone being dangerous, I believe. A. Yes, I——

Q. Unless given under the prescription of a physician?

A. Under the guidance of a physician, yes, and prescription.

Q. Now, on that subject of danger, do you consider testosterone [62] any more dangerous than bromo seltzer? A. Yes.

Q. Isn't it a fact that bromo seltzer is sold over the counter at soda fountains?

A. I am sorry to say that it is.

Q. And isn't it a fact that there are people in mental institutions right now that are there because of bromides that they have taken, in excess amounts?

A. Well, I don't know the fact. I know that people go to mental hospitals from overdoses of bromides. I don't know whether there are any bromo seltzer bromide poisonings today in a hospital.

Q. Well, an excess of bromides can cause mental derangement, can it not? A. Yes.

(Testimony of Clinton H. Thienes, M.D.)

Q. And bromo seltzer contains bromides?

A. That is right.

Q. And you are familiar with the fact, are you not, that there are many, many people that take bromo seltzer practically every day, if not certainly every day?

A. Yes, there are such people.

Q. Will not an excess of, take the product Alka Seltzer, tend in the long run to cause alkalosis in persons that are taking that excess?

A. Yes. [63]

Q. And that is sold over the counter, too?

A. Yes.

Q. Without prescription? A. Yes.

Mr. Elson: That is all. Wait just a moment. Doctor, I have one other question:

Q. In your experience, did I understand you to say that you had engaged in private practice?

A. I have.

Q. And having patients of your own or consulting? A. Both.

Q. How long have you been in private practice, in the handling of patients of your own?

A. I had a private office from 1942 until September of last year.

Mr. Elson: I have no further questions.

Redirect Examination

By Mr. Danielson:

Q. Just to clear up a couple of points, Doctor:

(Testimony of Clinton H. Thienes, M.D.)

What do we mean by palpation, Doctor? Palpation.

A. Palpation in medicine, medical parlance, is the examination of a patient by feel.

Q. An examination, a palpation of the prostate, would mean feeling of the prostate?

A. Yes. [64]

Q. What is the meaning of metastasis, Doctor?

A. A metastasis of a cancer is a cancer that has developed at a position different from the origin by some of the cancer cells at the site of origin, breaking loose from the original tumor and being transported to some other part of the body by lymphatics or blood, so, a metastatic cancer is a cancer at some part of the body different from the site of the original cancer.

Q. Now, you have mentioned palpation of the prostate. Is it possible, Doctor, to diagnose a carcinoma of the prostate by palpation at an early stage?

A. Yes.

Q. At an early enough stage so that beneficial therapy can be administered?

A. Oh, yes.

Q. Could that be early enough to avoid aggravation by the use of testosterone?

A. I am not sure that I am following your question there.

Q. At such a stage, when you could diagnose the carcinoma by palpation, would that be early enough so that it would be a contra-indication to the use of testosterone?

A. Yes.

Q. Now, certain symptoms were mentioned in your cross-examination, namely, flushes, sweats,

(Testimony of Clinton H. Thienes, M.D.)

nocturia, inability to [65] concentrate, irritability, in males of about 50 years of age. Would those symptoms be present in diseases or conditions other than hormone deficiency?

A. Yes, in most instances those symptoms are due to something other than hormone deficiency.

Q. Could you explain that, please, or give an example?

A. Well, in exophthalmic goiter or toxic goiter these symptoms would occur, in fatigue states, in anxiety states, they are common in tuberculosis, you will find that type of symptom complex.

Q. Would those conditions respond favorably to a testosterone therapy? A. No.

Q. What would be the effect of such therapy, in such cases?

A. It would be the same as in any other patient, that is, there would be the danger of producing sterility; or if there were a cancer present, of exaggerating it, cancer of the prostate.

Q. Upon the basis of your experience, practice, learning and education, Doctor, have you found—do you know whether persons in their late forties or fifties, persons with these specific symptoms, tend to diagnose them themselves?

A. Very often.

Q. What is the usual result of that, Doctor?

A. Well, they sometimes try to medicate themselves, treat themselves, such as buying testosterone, thinking that they have a deficiency of testosterone secretion, when they have one of these other diseases,

(Testimony of Clinton H. Thienes, M.D.)

and they would try to treat themselves in some instances to the point where the disease process has gone so far that it is difficult to treat satisfactorily.

Q. But you have mentioned, Doctor, that the testosterone is of therapeutic value where there is a deficiency in testosterone in the normal supply in the body? A. Yes.

Q. How is it determined whether or not there is an adequate supply of natural testosterone?

A. The only sure way that I know is to make hormone tests.

Q. And how are they done, generally speaking?

A. Well, it is a laboratory procedure.

Q. Does it require any special training?

A. It requires very special training.

Q. Now, Doctor, in connection with some of the literature which was brought to your attention, there was a statement in substance that the use of testosterone may produce a certain effect. Doctor, what is the significance of the word "may" in scientific and medical literature of that type?

A. Very often a physician in writing a paper, or in [67] giving a talk or in lecturing to students, will use the word "may" in the sense that a given situation occurs in let us say 10 per cent or 20 per cent of a given type of circumstance; so that a particular individual then has that probability of fitting in with the described condition and so the doctor will use the word "may" in that circumstance, meaning that there is a probability that this

(Testimony of Clinton H. Thienes, M.D.)

particular patient may respond in a certain way or have a certain condition, that is, he uses "may" in the terms of based upon known frequency of occurrence.

Q. There was a question asked, Doctor, to the effect that the use of testosterone might be it meant a choice of giving up a certain amount of fertility, in exchange for some benefits to be derived from the use of testosterone, to which you replied in effect that is true, but other circumstances must be taken into consideration. What would be such circumstances, Doctor?

A. Well, I think that the most—at least the thing that comes to my mind is the natural desire of every male to retain his potency; he may wish another child.

Q. Would the toxic effect have any bearing at that point? A. Toxic effect of what?

Q. Of the testosterone?

A. I don't see a relation. [68]

Q. With relation to carcinoma of the prostate, for example?

A. Well, of course, he would not be interested in developing a carcinoma of the prostate. I did not have that in mind, in my answer at the time.

Q. Now, Doctor, there was an article by Dr. Walter M. Kearns, "Testosterone in the Treatment of Testicular Deficiency," and prostatic enlargement was mentioned, and a portion was read therefrom. I direct your attention to the statement which was read, "Cherney has recently brought

(Testimony of Clinton H. Thienes, M.D.)

about the correction of abnormal libido in a male sexular criminal by the administration of large doses of stilboestrol, the synthetic estrogen."

What is stilboestrol, Doctor?

A. Stilboestrol is a synthetic or artificially prepared estrogen.

Q. That is one of the female hormones, is that correct?

A. It has the effects of the natural female hormones, but it is an absolute, entirely artificial preparation. It is a laboratory preparation.

Q. And in the same sentence he uses the expression "abnormal libido." What is the significance of that, in plain English?

A. Libido? [69]

Q. Is it abnormal?

A. Well, it might be a number of things. Libido itself is sexual desire and there are various and sundry types of abnormal libidos.

Q. Then, in the same connection, in connection with the same experiment, was the phrase there also occurring, "a cessation of spermatogenesis." What is the significance of that?

A. A spermatogenesis or cessation of spermatogenesis is the ceasing or stopping of the manufacture of spermatocytes, or as we ordinarily call them, sperm cells.

Q. Is there any respect in which that does not agree with your position that the use of hormones might decrease fertility at least?

A. No, no.

Q. Now, there is one more expression in this same article, at the bottom of page 928, of which I quote:

(Testimony of Clinton H. Thienes, M.D.)

“One of the contra-indications for the administration of testosterone is the desire in a young man simply to enhance his sexual power. There is apt to occur not only a lessening of the sexual power but a depression of spermatogenesis as well.”

Does that in any respect differ from your opinion, Doctor? A. Not at all. [70]

Mr. Danielson: No further questions.

The Court: Is there any recross?

Mr. Elson: That is all.

Q. (By the Court): However, Doctor, how would a doctor (by that I mean a physician, the ordinary family physician) determine approaching sterility in a case?

A. Well, there are several factors that he would take into consideration. One is the inability of the man and his wife to have children.

Q. Yes.

A. Second, the lack of sexual potency, the inability to perform the sexual act and, third, the actual examination of the seminal fluid to determine the number of spermatozoa present and the degree of motion. [71]

* * *

The Court: As to the progressiveness of sterility, it would require a chemical examination from time to time, would it?

A. Not necessarily a chemical examination for sterility, but it would require an examination of

(Testimony of Clinton H. Thienes, M.D.)
the seminal fluid from time to time. That is a laboratory procedure.

The Court: I don't have it in mind now and you may have told it but, if you did, I have lost it. Just how was it determined that the use of this drug would cause sterility?

A. Well, by the procedures which I have just outlined. Particularly, the laboratory procedure is the examination of the sperm. I am wondering if you are thinking of the diagnosis of male climacteric or a failure of secretion of testosterone.

The Court: Perhaps so but I got the impression firmly fixed in mind that you testified that the use of testosterone would be very likely to cause sterility in many cases. What I am inquiring is how was that determined.

A. The frequency with which this occurs, of course, is a matter that had to be worked out in a well-organized clinic, where a large number of patients could be studied.

The Court: Patients who were using it from day to day?

A. Yes, and under the doctor's direction.

The Court: And it was in that manner determined that it [72] did have that effect?

A. That is right. That had, of course, been discovered in the experimental animal before it was known in man. It was the results of experimental animal laboratory work that led the doctor to examine his patient to determine whether the same effects were happening in the patient.

(Testimony of Clinton H. Thienes, M.D.)

The Court: And it was also determined by the type of libido?

A. That testosterone would affect the libido in the individual who has a deficiency in secretion of testosterone; yes. I am not sure that I understood your question. Testosterone has an effect upon the libido but we don't study libido by examining the sperm.

The Court: That is all.

Mr. Danielson: That is all for the government.

Recross-Examination

By Mr. Elson:

Q. Doctor, what is the cost of a laboratory examination to determine whether a person is sterile or not? I mean, if a person goes to a doctor for some reason and the doctor is of the belief that testosterone might be the thing for him and so he has an examination conducted to determine whether the man is sterile, what would be the cost of such examination?

A. Just to examine the sperm would cost, I think, in the neighborhood of \$5.00. [73]

Q. I am speaking of the total cost.

A. You will have to repeat your question. I am afraid I didn't understand it.

Q. Would the doctor do it himself?

A. The doctor could do it himself, certainly, if he knew how.

Q. In connection with the examination for determining whether or not there is a hormone de-

(Testimony of Clinton H. Thienes, M.D.)

ficiency, before prescribing testosterone, what would be the cost of that procedure?

A. Fifteen to twenty-five dollars.

Q. That would be a sample of the urine, would it not? A. Yes.

Mr. Elson: That is all.

Mr. Danielson: That is all.

Dr. Warren Nelson, please. [74]

WARREN NELSON, M.D.

a witness called and sworn for the government, testified as follows:

The Clerk: Will you state your name?

A. Warren O. Nelson.

Direct Examination

By Mr. Danielson:

Q. Where do you live, Dr. Nelson?

A. Iowa City, Iowa.

Q. And what is your present occupation?

A. I am professor of anatomy in the College of Medicine at the University of Iowa.

Q. Of what schools are you a graduate, Doctor, and in what years and what degrees do you have, please?

A. In 1928, the Augustana College of Augustana, Illinois, Bachelor of Arts; 1929, University of Iowa, Master of Science, and, in 1931, New York University, Doctor of Philosophy.

(Testimony of Warren Nelson, M.D.)

Q. What was your specialty or major in your Doctor of Philosophy, Dr. Nelson?

A. Physiology and anatomy, a combined program.

Q. What post-graduate training have you had?

A. For two years, I studied as a National Research Council fellow at the University of Chicago with Dr. A. J. Carlson and Dr. Carl Moore.

Q. And what type of training did you receive there, [75] please?

A. I continued my training and endocrine studies, endocrinology, with Dr. Carlson and Dr. Moore.

Q. And what scientific or medical societies, if any, are you a member of?

A. I am a member of the American Association of Anatomists, the American Biological Society, the American Cancer Society, the Association for the Study of Internal Secretions, the Society for Cancer Research, the Society of Experimental Biology and Medicine and the Johnson County Medical Society, which is our local society.

Q. You have testified, Doctor, that you are presently professor of anatomy at the University of Iowa Medical College, is that correct?

A. Yes, sir.

Q. How long have you been so affiliated?

A. I have been at the University of Iowa five years.

Q. Did you previously have any teaching affiliations?

(Testimony of Warren Nelson, M.D.)

A. Yes; at the College of Medicine at the University of Missouri.

Q. What was your capacity there?

A. I was assistant professor of anatomy there. I held the same post, assistant professor of anatomy, at Yale University, College of Medicine, and I was professor of anatomy and head of the department at Wayne University, College of [76] Medicine, at Detroit.

Q. How long were you there in that capacity?

A. Two years.

Q. In what fields do you teach medical students?

A. Human anatomy and endocrinology.

Q. Are those the fields in which you specialized, Doctor? A. Yes, sir.

Q. Do you make a practice, Doctor, of studying and reading the literature in your field of endocrinology? A. Yes.

Q. And do you from time to time confer with and discuss with other scientists and doctors as to this subject matter?

A. Yes, sir; very frequently.

Q. Will you explain the meaning of the term endocrinology, Doctor?

A. It is a study of the endocrine glands or of the glands of internal secretions. These are certain glands of the body whose products are released direct into the blood stream.

Q. Will you name some of them?

A. The testes, which are under discussion, the

(Testimony of Warren Nelson, M.D.)

ovaries, the pituitary, the gland in the head, the adrenals, the pancreas and the thyroid. [77]

Q. About how many scientific papers have you had published on the subject of endocrinology?

A. Something on the order of 150, I believe.

Q. Would you name a few of the representative publications in which they have been published, please?

A. The Journal of Clinical Endocrinology, Endocrinology, American Journal of Anatomy, Anatomical Record, Proceedings of the Society of Experimental Biology and Medicine.

Q. Have some of these papers related to the function of the testes? A. Yes.

Q. About how many, Doctor?

A. Oh, 25 to 35, I would estimate.

Q. Have you done any investigation into the use of testosterone? A. Yes.

Q. And its effect on the function of the testes?

A. Yes.

Q. How extensive has been your research in that line, Doctor?

A. It has covered a period, I would say, of 15 years. In the days before we had testosterone as a purified chemical, we were using extracts of bull's testes or human urine, on up to the present time, when we have highly purified products. [78]

Q. What has been the object of this research, Doctor?

A. To determine the function of the testes and the factors which control the function of the testes.

(Testimony of Warren Nelson, M.D.)

Q. Has any of this been to determine the effect of testosterone on the testes? A. Yes.

Q. Has any effort been made by you to determine the effect of testosterone on other parts of the body besides the testes? A. Yes.

Q. Doctor, in conducting your investigations, has it been your policy to consult with medical doctors on the staff of your university and assisting them in making diagnoses and recommending treatment in cases of testicular disfunctioning or other endocrine conditions?

A. Yes; our own medical staff and the medical staffs in other universities as well.

Q. Will you kindly describe to the court, Doctor, the investigations of this nature that you have conducted?

A. Is it at this point that you would like to have me——

Q. Will you kindly describe to the court, Doctor, on the basis of your education, your training and experience, your study, your consultations and discussions, your clinical and laboratory research, the sum total of your experience along this line, particularly the effect of testosterone on [79] the testes or other parts of the anatomy? What is the effect of testosterone?

A. These studies have embraced not only studies on human patients but also studies on experimental animals. The forms of procedure or general procedure that we have followed in the case of the studies on human testes is to obtain a sample, a

(Testimony of Warren Nelson, M.D.)

biopsy, of the testes, in fact both testes, prior to treatment, and then to administer the hormone over a definite period of time, at the end of which a second biopsy would be obtained and compared with the first biopsy. At the same time, studies would be made upon hormonal levels of the urine and these would include studies of the byproducts of the male sex hormone, testosterone, and the levels in the urine of hormones called gonadotrophins. These are substances produced in the pituitary gland, a small gland in the head. These gonadotrophins are all essentially a normal function of the testes. The injection of testosterone will inhibit the activity of the pituitary in the production of these gonadotrophins and this will, in effect, bring about a condition of hypophysectomy. That is a condition in which the pituitary is removed or absent. The same would be true of estrogen; it will inhibit the production of these gonadotrophins and that is a definite function of these testes normally. The result is a lowered production of spermatozoa and a lowered production of the hormones of the testes. [80]

Q. In this inhibition of the gonadotrophins, Doctor, are you referring to the natural supply of testosterone within the body or that administered from some independent source?

A. In this case, I am referring to the administration of testosterone. However, I think it is proper to say that in the normal functioning of the pituitary testicular axis there is an interplay be-

(Testimony of Warren Nelson, M.D.)

tween the testicular hormones and the pituitary hormone. As the pituitary hormone drops, the testicles would no longer be stimulated properly and thus the level of the testicular hormone testosterone would drop and the pituitary would then go into greater activity. It is an action like a thermostat. When the heat drops, the thermometer there records it and turns the furnace on. As the testes hormone level drops, the pituitary is turned on to produce more gonadotrophins. However, if the level of the testosterone gets too high, then the activity of the pituitary is lessened just as when the temperature in the room gets too high the furnace is turned off.

Q. In other words, is this correct, that the gonadotrophins have some effect on the testes?

A. That is right.

Q. And their effect is to do what?

A. To stimulate the testes to produce spermatozoa and to produce testosterone. [81]

Q. And then, when the testosterone level increases, what effect does that have on the pituitary?

A. That inhibits the pituitary's activity in the production of these gonadotrophin hormones and thus would decrease the activity of the testes both in the production of the spermatozoa and in the production of testosterone within the testes.

Q. For how long a time would this inhibition last, more or less?

A. Certainly for the duration of treatment. How much beyond that it is difficult to say.

(Testimony of Warren Nelson, M.D.)

Q. Have you, as a result of your experiments and studies made any determination as to what ultimate effect that has upon the testes?

A. In the case of human testes, the result will depend a great deal upon the condition of the testes at the time the administration of testosterone is begun. If the testes are entirely normal, as determined by this pretreatment biopsy, the effect is less marked, though very evident, than in the case of testes which are not entirely normal, which have undergone certain changes, particularly in the connective tissue around the tubules of the testes. Testes that have that type of damage are very definitely and rapidly damaged when testosterone is administered.

Q. Is this damage a permanent effect? [82]

A. I cannot as yet answer that question to my own satisfaction but I think probably not unless the damage before treatment in the testes is present and treatment is continued for, say, five or six months.

Q. Doctor, have you made in connection with these experiments any determinations as to sperm levels?

A. Spermatogenesis is affected by the administration of the testosterone. However, I am reluctant to place complete dependence on sperm counts unless many, many of them are taken. There is quite a fluctuation from day to day or often week to week in the same individual and many counts must be taken to establish a norm. I feel that a

(Testimony of Warren Nelson, M.D.)

sample taken and studied with greatest histologic detail reveals much more than do a few.

Q. On the basis of your experiments and your education and training and research, do you have an opinion as to the effect of testosterone therapy on fertility or sterility?

A. Yes; at the present time I would say all evidence that we have been able to accumulate indicates that a level of testosterone which will have an effect on the testes, and by that I mean 20 to 25 milligrams a day, indicates it will cause damage to the testes, the extent of the damage being determined by the pretreatment condition of the testes.

Q. On the basis of your research, Doctor, do you have an opinion as to the frequency of damage to the testes in men [83] in their fourth or fifth decade?

A. Well, as men get older, the testes show the ravages of time and they are more prone to be in an atrophic condition, so that a man in the fifth or sixth decade of life would be more likely to have testes which are already showing some damage and, therefore, be more susceptible to the damaging influences of testosterone.

Q. Doctor, as to this information you have just given us, do you include this in your teaching to your medical students in whole or in part?

A. Yes; in general essence, we give them these details, though I have had more occasion to dis-

(Testimony of Warren Nelson, M.D.)

cuss these matters with medical societies and medical groups in various parts of the country.

Q. Doctor, in connection with your discussions with medical societies and medical groups, have you had any method of illustrating and establishing the interplay of the various secretions, as you have just described them to us?

A. Yes. We commonly use what are known as lantern slides, with pictures of either diagrams or histologic material which has been collected in the course of the studies.

Q. Did you bring some of those slides with you, Doctor?

A. Yes, sir.

Q. Were they prepared in connection with this case or in connection with your regular work? [84]

A. They were prepared in connection with my regular work and have been used many times in other connections.

Q. That was before you heard of this case, is that correct?

A. Yes, sir.

Q. Did you bring any of those slides with you, Doctor?

A. Yes, sir.

Q. Were they made by you or under your supervision and direction?

A. Yes, sir.

Q. And are they an accurate portrayal of that which they purport to portray?

A. I think so.

Q. Would it help, Doctor, to explain the results of your experiments by projecting them?

A. I think some of the points I have attempted

(Testimony of Warren Nelson, M.D.)

to make could be a little more graphically obtained if they were used.

Mr. Danielson: Your Honor, we have in court various of these slides that Dr. Nelson has referred to. We also have a slide projector set up and a screen here. We should like to offer them, your Honor, at the present time, subject to cross-examination as we go along, if counsel wishes, and subject, of course, to the motions made earlier today by counsel for the defense to strike in the event they do not apply. With the permission of the court, we should like to project them. [85]

The Court: Very well. Proceed.

A. If we can have the lights off, we can use the wall and it will be more evident, if that is permissible.

Mr. Neukom: Oh, surely.

A. That is backward. The red spot should be on top and to the right. Just to locate the area of the testes and some of the things it affects, this is a saggital section through the body, the testes in the scrotum, and some of the structures which are affected by testosterone are this sperm duct, the epididimus passing up here, the prostate, which is this area here connected with the bladder, the seminal vesicles, which also contribute to the seminal fluid, and then the penis. The next slide, please. Oh, yes; if there are any questions, please ask them.

Q. If there are any questions, you may ask them.

Mr. Elson: I haven't in reference to that slide.

A. This is a diagrammatic section through the

(Testimony of Warren Nelson, M.D.)

testes, indicating tubules which produce the sperm. And they can be seen in orderly progression from the basement membrane here up toward the center of the tubules, these black elements being the mature sperm or male germ cells. I would like to call attention to this thin line around the base of the tubule. This is what is called the basement membrane and with change or disease or atrophic condition of the testes, [86] this becomes very thick and interferes with the passage or intrusion from these areas outside of the tubules into the germ cells. Like all epithelia, there are no blood vessels in the germinal epithelium. Nutritive materials or food materials must pass through this material, in through the center of the tubule, and, if that thickened as it has in cases of testicular atrophy, then a further atrophic change is brought about because of the ineffective passage of food materials. In the space between the tubules are cells that we call interstitial cells. It is these cells which produce the testosterone we have been hearing about today. May we go on with another slide? This, I think, shows well the pituitary testicular axis that we mentioned, the pituitary here shown diagrammatically, with two hormones, the FSH hormone and the ICSH, that is to say the follicle stimulating hormone and the interstitial cell stimulating hormone. This is to represent the testes and its two components, tubules and interstitial cells. The FSH factor stimulates the tubules producing spermatazoa. The ICSH factor or hormone stimulates

(Testimony of Warren Nelson, M.D.)

the interstitial cells to produce testosterone. As we said before, there is an interplay between the testosterone produced in the testes and pituitary. If the level of testosterone gets high, it shuts off the production of these gonadotrophin hormones FSH and ICSH and, as a consequence, the target hormones of the testes are not stimulated. [87] The level of the testosterone drops. Then the pituitary springs into activity and these hormones are secreted and again we have the testes stimulated. I think it is important to bear in mind that balance, that sort of a thermostatic arrangement between the testes and the pituitary.

Q. One question. This pituitary gland is situated where in the body, Doctor?

A. It is in the head, commonly said to be at the base of the brain. It is a very small gland, not much larger than a good-sized pea but it is a very important gland because it produces hormones other than those I have mentioned here, hormones that are important in controlling the function of the thyroid, the adrenals and probably the pancreas. This shows, in essence, again what I have just gone through and a little more graphically. There is the general shape of the pituitary up there. This is the testes. These are two parts of the testes, seminiferous tubules and interstitial cells. The tubules, of course, produce the sperm and the interstitial cells producing testosterone. And testosterone has many effects on the body both in the growth of the

(Testimony of Warren Nelson, M.D.)

beard and distribution of hair, including scalp hair, muscular growth, growth of the penis and other organs of male reproduction. [88]

The Witness: This slide shows the changes through puberty, from the pre-pubertal boy to the adult man, and as the testes increase in size they produce the testosterone that causes growth of the penis, it causes the growth of body hair, the ciliary hair and pubic hair and causes growth of the muscles, it causes enlargement of the larynx so that the voice changes, appearance of the beard and recession of hair in the scalp region.

And down here, the growth of the prostate. And, of course, the prostate will not grow without testosterone.

Next, just to illustrate the point, I tried to make about the importance of this interplay between the pituitary gland and the testes, these slides are slides taken from the entire reproductive system of laboratory animals, in this case the rat, the testes. Here is the sperm duct, the sperm ducts, the seminal vesicle, the prostate here at the base of the bladder—and there are other glands that we won't bother to name now—this is the reproductive system of a normal adult male rat. It looks very much like the same system does in the human being.

Next. Now, if that pituitary gland is removed by surgical operation, then the testes become atrophic, and the injection of the gonadotrophic hormone will restore them to normal. If the pituitaries are removed, then the sperm are not pro-

(Testimony of Warren Nelson, M.D.)

duced and the hormones of the testes are not produced, but both [89] of those functions, sperm and hormone production are restorable by giving injections of pituitary extracts.

However, next, in such an animal, without its pituitary, the pituitary hormones are injected by means of extracts. Then, the hormones which were removed by the removal of the pituitary are again supplied and the testes are returned to normal, they again produce sperm, they again produce hormones by the growth of the seminal vessels and the prostate.

Now, to transfer this briefly to the human being, there are conditions in men in which the pituitary fails to function normally in producing the gonads, stimulating hormones. We call such individuals eunuchoids. They are castrate-like individuals. Those individuals fail to go through puberty, and if we take a sample of their testes (this was done in this case) we find the tubules are very small, they are like the tubules of a boy before he enters puberty. In the space between the tubules there are no interstitial cells and, consequently, the individual is producing no testosterone and as a consequence he does not go through puberty. In such an individual we recognize them expressly only by taking a sample of the testes and seeing its picture, and if such an individual is given gonadotrophic hormone, then, in five or six months this picture can be produced in essentially normal testicles with tubules producing sperm and interstitial

(Testimony of Warren Nelson, M.D.)

cells in between these spaces between the tubules, and such an [90] individual passes through puberty under the influence of this stimulus to the testes.

Q. (By Mr. Elson): Doctor, did I understand you to say that with a eunuchoid or a person who was not passing through puberty, or not developing there, that the administration of testosterone would tend to make those cells in the testes grow towards normal and he would tend to become more of a normal person?

A. No. I said that gonadotrophic hormone, a gonad stimulating hormone, the gonadotrophic hormones are the ones that are missing and therefore they are the ones that we attempt to supply.

Q. Let me ask you this, though, isn't it customary with a eunuchoid to administer testosterone to him?

A. It is not in the case of our group. We first determine the condition of their testes and see whether we can't make the patient's own testes produce testosterone.

Q. But the literature is quite replete with instances wherewith eunuchoids they have injected testosterone, isn't that true?

A. In some eunuchoids, and we can determine such eunuchoids by getting a sample of the testes or by making certain urine tests. In some eunuchoids the testes are not susceptible to stimulation. When that is the case, when there is a failure of the testes, then it is proper to give testosterone, but

(Testimony of Warren Nelson, M.D.)

if [91] there is a failure of the pituitaries, the pituitary serum should be given.

Q. In the majority of cases, would you say that testosterone is not administered?

A. I would say in the majority of instances the testosterone has been administered, in some instances incorrectly because the case was not properly diagnosed. But we are just coming now to recognize the differences in these eunuchoids and ways in which to differentiate between them.

Mr. Danielson: You are not speaking, Doctor, solely of the eunuchoid group, though, is that not correct?

A. That is right. I am speaking about eunuchoids now.

Q. (By Mr. Elson): When you say you are just coming now to do that, what do you mean?

A. Well, five years, that isn't very long in terms of medical history.

Q. I understand. That is all. I was sorry to interrupt you.

A. It is quite all right.

Now, to go in reverse, showing that testes can be stimulated by gonadotrophins—that pituitary hormones would stimulate the testes, what happens in the human testes, I have shown where gonads are removed. For example, here is a biopsy taken from a testes of a man in which treatment of estrogen had been indicated. This testes is fairly normal. It produces fair quantities of spermatozoa and it has interstitial cells in the intertubular area. If estrogen is given, this picture is produced, in three

(Testimony of Warren Nelson, M.D.)

or four months a very remarkable and rather complete atrophy of the testes, the reason being that the patient's pituitary was inhibited from the production of hormones that the testes require. This is a case of before and after treatment with estrogen.

However, androgen will do essentially the same thing. This was a pre-treatment biopsy and, three months later, after daily treatment with 25 milligrams of testosterone, the tubules show the evidence of a lack of the pituitary stimulating hormones.

The same is true of the interstitial cells of life, the hormone producing cells, they no longer are normal in function or appearance.

Q. The 25 milligrams you speak of per day, that was injected?

A. That was given by injection, yes, sir.

Next, please.

These are some larger views, pre-treatment condition.

These are the sperm-producing areas, the tubules.

These are the interstitial cells that produce the testosterone, big, fat healthy cells and very evidently functional in appearance.

Next, please. [93]

The same case three months later, after treatment, again with 25 milligrams of testosterone a day, and the atrophic change in the tubules, as well as in the interstitial cells. This latter patient, I forgot to say, had rather definitely normal testes

(Testimony of Warren Nelson, M.D.)

throughout. The biopsy showed a normal picture.

This is a third biopsy taken three months later, after the cessation of treatment, showing that the interstitial cells have returned to normal and the spermatozoa are again present.

Next.

This, again a pre-treatment and a post-treatment picture of the human testes, biopsies again taken from a living individual, before treatment with testosterone and after. This testes was not quite as healthy before treatment and therefore the changes were a little more remarkable and the recovery less remarkable as well.

Next, please.

Now, this is a little bit different case, but I show it simply to emphasize the similarity in appearance between the testes of individuals whose pituitaries have been inhibited by giving androgens or estrogens and testes from individuals who exaggerate, in another way stopped the production of or the action of the gonad stimulating hormones.

I shall not go into the details except to tell you that [94] that is a pre-treatment biopsy and the biopsy taken during treatment and it was a case in which we produced or caused to be produced what we call anti-hormones, hormones which inhibit the activity of the gonad stimulating hormones and that is, when that is done, the testes show this picture which is, as I said, similar to that seen in individuals whose pituitaries have been inhibited from producing the gonad stimulating hormones.

(Testimony of Warren Nelson, M.D.)

Next.

This is the last one, is it?

The Machine Operator: Yes, sir.

The Witness: We will return to a laboratory study, finally. This is a picture of the testes in a rat of 30 days of age. This is just before they go into maturity.

This is a picture at 60 days and this testes is quite mature.

Now, if, at 30 days of age that animal is treated with testosterone, for 30 days, this is the picture that is seen at the end of 30 days, in other words, when the animal is 60 days of age. You see, the testes, instead of maturing from this state to an adult state, it has been halted in the immature condition and has failed, again, to undergo maturation.

However, if at the same time as the testosterone is injected, gonad stimulating hormone is given to the same animal, [95] testosterone plus gonad stimulating hormone——

The Court: What, then, did you say should be given to stimulate?

A. In this case, if I have not made it clear, please tell me again.

The Court: Yes.

A. This animal, at 30 days of age, was given testosterone but at the same time was given gonad stimulating hormone from the pituitary.

The Court: Say it again.

A. Gonad stimulating or gonadotrophic. The

(Testimony of Warren Nelson, M.D.)

hormone is the pituitary that normally stimulates the testes.

The Court: Yes.

A. If it is given along with the testosterone, the development proceeds normally.

Now, the point here to bring out is that when testosterone is given, the testes fail to develop symptoms of this state (indicating). This condition is obtained (indicating). The reason being is that the testosterone inhibits the pituitary from producing these gonadotrophic hormones. But, if in such an animal, that is in an animal whose gonadotrophic hormones have been inhibited, if the gonadotrophic hormones are injected, that is, by extracts made of the pituitary, then, even though the animal's pituitary can't stimulate the testes, the injected hormones do, and we get the picture that normally [96] should have held at the end of those 60-day periods of life. In other words, these two pictures purport to be similar.

Well, I have just simply attempted to——

The Court: What is the gonad?

A. I guess the "gonad" may have been misleading. The gonads are generic terms for the sex glands, either ovaries or testes. It is spelled g-o-n-a-d. And the term gonadtrophic simply means gonad stimulating substances.

* * *

Q. (By Mr. Danielson): Dr. Nelson, on the

(Testimony of Warren Nelson, M.D.)

basis of your education, your professional training and experience, your research, your studies of the literature and conferences with other scientists and doctors and consultations and the research which you have just so graphically portrayed for us, what is your opinion as to the effect on the testes of administered testosterone? By administered testosterone, I am referring to testosterone other than that produced within the body.

A. On the human testes——

Mr. Elson: Wait a minute. Doctor, I want to confine that to methyl testosterone that we are talking about in this case. [97]

Mr. Danielson: Very well, to methyl testosterone, the effect of methyl testosterone.

A. From my own researches, I cannot make any statement on the effect of methyl testosterone.

Q. (By Mr. Danielson): Can you make an opinion on the basis of your professional training, experience, education, your studies of the literature and the results of your conferences and discussions with other scientists and doctors, as to the effect of administered methyl testosterone on the testes?

A. Yes. For instance, methyl testosterone has quantitatively the same effect as testosterone, the effect on the testes is the same.

Q. What would that effect be?

A. The inhibition of sperm cell production and the inhibition of the production of testosterone by the interstitial cells.

(Testimony of Warren Nelson, M.D.)

Q. Would potency as such be a valid indication of whether the interstitial cells producing testosterone are or are not functioning under those conditions?

A. No, because the administered testosterone would, of course, provide the necessary chemical agent for the induction of potency, in other words, the administered testosterone would take the place of the individual's own testosterone, which is no longer being produced in the same [98] amount as before treatment.

Q. How could it, then, be determined whether or not there had been any damage to the testosterone-producing portions of the testes?

A. The only way one can ascertain that is by examination of the testes and looking at the interstitial cells, noticing the atrophic changes that have been promoted by the inhibiting influences of the administered testosterone.

Q. Is that the microscopic examination of a slide a portion of the testes——

A. Yes, sir——

Q. Under a slide? A. Yes, sir.

Q. (By the Court): Just how do you get at that? How do you examine the testes under a slide?

A. A small piece of the testes is removed.

Q. (By the Court): By surgical operation?

A. By surgical operation, usually under a very simple local anesthetic. The tissue is properly

(Testimony of Warren Nelson, M.D.)

fixed and sectioned and stained, the usual pathological procedure.

Q. (By the Court): How would that be called for except by just some experiment? That does not seem like a practical thing? Who would have that done?

A. It is being done very, very widely, now.

Q. It is? [99]

A. In cases of infertility or sterility or suspected disease or abnormal function of the testes. It is a widely recognized procedure at the present time.

Q. (By the Court): What prompts it? That is, is it in any sense an examination to determine a cancerous condition?

A. No, not of the testes. Cancer of the testes would usually be evident by rapid growth and swelling of the testes and biopsy would not likely be indicated.

Q. (By the Court): Well, this is the surgical operation, you call that a biopsy.

A. A biopsy is a surgical process or operation in which small samples of the tissue is obtained.

Mr. Danielson: No further questions.

Cross-Examination

By Mr. Elson:

Q. Doctor, you stated among your last answers there that you had had no experience yourself regarding the effect of methyl testosterone on the testes.

A. On the human testes, yes.

Q. Yes, but then Mr. Danielson asked you a question, with a long preliminary about your con-

(Testimony of Warren Nelson, M.D.)

tact with others and so on and, as I understood, your answer was that as a result of that, the opinions of these others were that methyl testosterone did inhibit the sperm production. A. Yes.

Q. Now, did you mean that, that in your opinion that is the concensus of opinion?

A. Yes. Yes, sir.

Q. Now, is there any relationship between impotence and sterility?

A. Not a necessary one. They may exist independently or concurrently.

Q. So, when you were speaking of sterility, did you have in mind impotence or simply sterility without regard to impotence?

A. Simply sterility.

Q. Now, is there any comparison (I don't know whether that is the right word or not), but is there any comparison or relationship between the effectiveness or activity of testosterone propionate, as distinguished from methyl testosterone, in the creation of sterility in an individual?

Do I make myself clear?

A. I think you mean is there a relationship per unit weight of material.

Q. (By Mr. Elson): Frankly, I don't know enough about the subject to frame a question that way. But what I mean is this: Your testimony has been that the concensus of opinion is that methyl testosterone inhibits sperm production and tends to cause sterility, am I right? A. Yes. [101]

Q. Now, does testosterone propionate or testos-

(Testimony of Warren Nelson, M.D.)

terone by injection tend more to cause sterility than testosterone administered orally such as methyl testosterone?

A. On the basis of other studies, where the effects of methyl testosterone and testosterone are compared and parallel studies, it requires more by mouth than it does by injection and, therefore, one would expect that it would take more methyl testosterone.

Q. How much more testosterone by injection—or I will put it this way: You part-way answered the question I had in mind next. How much more testosterone by injection would tend to cause sterility in the average case?

A. Any answer I would make there would be purely an estimate and not based upon enough——

Q. It would be conjectural?

A. (Continuing): —scientific information, to warrant it.

Q. (By Mr. Elson): Would you say that 25 milligrams injected three times a week would in the average person tend to cause sterility?

A. It would reduce the production of spermatozoa, it would make him less fertile. I would be unwilling to say that it would make him sterile. Sterility implies complete lack of fertility.

Q. Wouldn't it then follow, Doctor, that 25 milligrams [102] per day in the form of methyl testosterone would even have less effect towards inhibiting sperm production?

(Testimony of Warren Nelson, M.D.)

A. In what type of case do you mean?

Q. Well, let us take a person, Doctor, whom a doctor has diagnosed as apparently suffering from going through the male climacteric or has the symptoms that are associated with that condition?

A. It would depend. The effect of the methyl testosterone or any testosterone would largely be determined by the condition of the patient's own testes. As I tried to show that, that is extremely variable and the degree of effect is conditioned by the degree of normalcy or abnormalcy of the testes.

Q. In other words, if I understand you correctly, is this about it? That if you would take a person such as the one that I have just described and if his testes were producing a very small amount of testosterone, would it be your opinion that the administration of the quantity of methyl testosterone that I have described here would tend to inhibit the sperm production?

A. That is difficult to answer, because you have not told me in your hypothetical case what the condition of his sperm production was before treatment was given.

Q. You mean by sperm count?

A. Sperm count, that would be one measure.

Q. Frankly, I wouldn't be able to include in any hypothetical question anything about sperm count, but let us say, can we put it this way, just generally: that the sperm count was low or the amount of testosterone produced by that individual's testes was low, would methyl testosterone in the quantities

(Testimony of Warren Nelson, M.D.)

that I have mentioned inhibit the production of sperm to the point that you could say that he was tending toward sterility or was going to become sterile?

A. If his sperm production was low, that would be a definite indication that damage had been done, had been undergone by the tubules and, therefore, a methyl testosterone or any testosterone would be more likely to cause damage than in an individual with a high sperm count.

Q. How about a person—can we take one with the average sperm count; let us take a person 50 years old with those symptoms, could we take an average sperm count regardless of what it is, and direct our question, then, to the effect of methyl testosterone on that person?

A. Speaking in general terms, I would say—I would say that the testes of such an individual would be less damaged than the man who had a very low sperm count.

Q. Doctor, what period of time in your opinion would it require for that dosage of methyl testosterone, with that individual, to damage the testes to the point that he became sterile? [104]

A. When you use the term sterile, you are using, as I mentioned a moment ago, a rather final term implying complete lack of fertility.

Q. Can we say non-fertility or not sperm-producing?

A. A completely sterile individual, a permanently sterile one would be one who no longer had germ

(Testimony of Warren Nelson, M.D.)

cells which were multiplying. However, an individual's testes may contain many germ cells and yet, that individual be sterile, and there are all phases and grades from that point on up to what we would regard as the normal testes with the normal germ cell population. So I can't answer in specific terms your question, for that reason. The difference seen between different individuals is extraordinary.

The Court: There would be an extinction, then, of evidence?

A. Yes. When the testicular hormones, testosterone, for example, is given, the production of the pituitary hormones that stimulate the testes is reduced and no longer do the germ cells tend to multiply, in fact, they tend to decrease in number and the degree of effect is not the same in every individual because the condition of the germ cells prior to treatment is so widely variable.

Q. (By the Court): That would not necessarily mean an utterly dead extinction?

A. No. That is right. That is quite correct. [105]

The Court: Both being generic?

The Witness: I have no way of saying——

Mr. Elson: I did not get what the court is referring to. I didn't get the court's question.

(Record read.)

Q. (By the Court): The diminuation of capacity to produce constantly reduced to where there was no production of——

(Testimony of Warren Nelson, M.D.)

Q. (By Mr. Elson): Well, coming back now, Doctor, to the allegations of the information, the information charges that 25 milligrams of testosterone, of methyl testosterone to be taken one tablet or two tablets a day of 25 milligrams per day, in the latter case, that it may cause sterility in the individual. From what you have just said, I take it that that term is incorrectly used, that it may cause sterility, but rather that it would cause an inhibition——

A. Yes, sir.

Q. ——of the growth of spermatozoa in a particular individual?

A. Sterility is a very broad term and I am attempting to define it here in my own terms as I use it in my contact with these individuals, the problems of fertility or sterility.

Q. Now, Doctor, let us leave the 25 milligrams for a moment. Let us assume that we have the same individual and the amount of the product is not 25 milligrams once or twice [106] daily of methyl testosterone but 10 milligrams, would you say that in such individual that 10 milligrams taken in tablet form once a day will really have any inhibitory effect in a material way on such an individual?

A. The likelihood is more remote in that case than in the case of 25 or 50 milligrams a day, but the possibility would exist I believe in the instance of the testes that is already showing signs of atrophy.

Q. Coming back to the point that I had in mind this morning when I asked Dr. Thienes, the inhibi-

(Testimony of Warren Nelson, M.D.)

tory effect on the individual would really be less, though, if he bought and took methyl testosterone himself—strike that.

Assume that a person went to a doctor and the doctor prescribed and injected testosterone propionate. The result is going to be the same, isn't it, on affecting the man's ability to produce spermatozoa as if he had gone to a drugstore and obtained a package of methyl testosterone himself and took it, except that which the doctor injected would tend to be more of an inhibitory agent, would it not?

A. Yes. Of course, in such an instance, I am sure the physician would have warned the individual of the possibility that his fertility would be decreased; he would know the possibility that he faced. If he treated himself, he would not know that.

Q. I beg your pardon? [107]

A. If the patient treated himself, he would not be aware of that possibility.

Q. Do you think that that is the general rule with the general, average practitioner, with a person who the doctor finds is suffering from symptoms associated with the male climacteric?

A. Yes, I think so. The physician has the well-being of his patient at heart and would explain to him the possible beneficial effects of the testosterone as well as its possible deleterious effects.

Q. Don't you think that 25 milligrams once or twice a day of methyl testosterone given to a patient such as I have described over a period of four, five,

(Testimony of Warren Nelson, M.D.)

six weeks, would tend to relieve those symptoms if he were suffering from a hormone deficiency in that period of time?

A. The relief from the symptoms of the male climacteric could be expected in about that time. However, mind you, I said in the case of a male climacteric. I agree with other testimony that has been given that it is an unusual and rarely encountered condition.

Q. So, would you say that if a person manifested those symptoms and took methyl testosterone for that period of time and those symptoms were relieved, that it would be a reasonable assumption that the man was going through the male climacteric? [108]

Mr. Danielson: Just one moment. I assume you are referring to the same symptoms which were brought out in the examination of Dr. Thienes, is that correct, that is, the flushes and so forth?

Mr. Elson: Oh, sure.

* * *

A. I would just like to generalize there. It undoubtedly is a procedure that is done in some instances. In our own case, for example, at the University of Iowa, where individuals come suspected of having the male climacteric, laboratory tests are made to determine whether or not he properly belongs in that category and can be benefited by giving testosterone, or whether he should receive other forms of therapy.

(Testimony of Warren Nelson, M.D.)

Q. (By Mr. Elson): Well, there is a differentiation, is there, between the method of a doctor in your position and others we will say associated with universities or experimental institutions, the method in which they approach a problem and the manner in which it is approached by the average general practitioner?

A. Yes, inevitably that is true. [109]

Q. The economic factors, the factor of time and probably many others enter into it? A. Yes.

Mr. Elson: I have no further questions.

Mr. Danielson: No further questions, your Honor.

Q. (By The Court): Just what is the meaning of the prefix methyl? In methyl testosterone, "methyl," why is that prefix?

A. Are you directing the question to me, sir?

Q. Yes.

A. Methyl I think Dr. Thienes described it this morning is a group of chemical grouping with one carbon and three hydrogens and it is affixed——

Q. I made a note of that at the time, but that does not mean too much to me.

A. Well, in the carbon ring, which is the structural arrangement of these hormones like testosterone, the methyl group is inserted into the ring replacing one hydrogen so that there is testosterone minus one hydrogen.

Q. By adding the carbon group?

A. But plus the methyl group.

Q. Yes.

(Testimony of Warren Nelson, M.D.)

A. The carbon plus the three hydrogens.

Q. Now, you stated, I believe, that this gonad——

A. Gonad—— [110]

The Court: Spell it.

A. G-o-n-a-d.

The Court: I thought it was g-n—gonad was a product of the pituitary gland.

A. The gonadotrophic or gonadic stimulating hormones are products of the pituitary.

Q. (By the Court): Well, is that a hormone generally produced for the market?

A. Yes, such extracts are prepared. They are quite different than the hormones testosterone or estrogen. *They protein* hormones prepared largely from animal tissues.

The Court: I gathered from what you said in explaining the slides there that if there was the definite amount of that hormone mixed with a treatment of the other, that it would have a beneficial effect and overcome deleterious effect of the other while given alone?

A. That is correct.

The Court: I wanted to get that.

The Witness: That was an experiment in which the pituitary hormone was given to replace the animal's own absent pituitary hormones which were absent because their pituitaries had been inhibited by the testosterone.

The Court: Yes. Are there any further questions?

Q. (By Mr. Elson): Just then the court asked

(Testimony of Warren Nelson, M.D.)

a question of Dr. Nelson about the difference or what methyl testosterone [111] was and, though this may answer what the court had in mind, I am going to try it and see if I am not right.

Doctor, testosterone propionate is injected intramuscularly, isn't it? A. Or subcutaneously.

Q. Yes. Methyl testosterone is in the form of tablets and taken orally in the mouth, isn't it?

A. Or they can be injected, too.

Q. Yes. They are usually done, though, some place on the body, aren't they?

A. A small incision is made.

Q. And a pellet is placed therein?

A. Pellets of free testosterone are implanted.

Q. And methyl testosterone is taken orally as a rule? A. Yes; I think more commonly.

Q. And testosterone propionate is injected intramuscularly or subcutaneously? A. Yes, sir.

Q. And isn't it a fact that testosterone propionate is much more potent in its effect than methyl testosterone? A. It is more effective; yes.

Q. In other words, if you will take 25 milligrams of testosterone propionate and inject it into a person, the effect of that would be considerably more than 25 milligrams of methyl testosterone taken orally?

A. It would be; yes. But I don't know what you mean by "considerably."

Q. What is the relationship? Would you say it was three, four or five or 10 times more effective, or is there any way of pointing it out?

(Testimony of Warren Nelson, M.D.)

A. One would have to there, I think, specifically say what activity of the testosterone you had in mind. In the case of the effect on the testes, I have no accurate comparative figures.

Q. This may be a little bit unorthodox in my manner of approach, but it is at least expeditious, I think. In trying to gather this material together, I ran across an article of Charles William Dunn. Are you familiar with that? [113]

A. Yes; I know Dr. Dunn.

Q. It is an article entitled "Diagnosis and Treatment of Testicular Deficiency, Male Hormone Therapy," by Charles William Dunn, in the publication Medical Clinics of North America, November, 1942, Volume 26, at page 1894, where he stated, "The oral preparation, methyl testosterone, has only from one-third to one-fifth the activity per milligram of injected testosterone propionate." Would that fairly reasonably in that connection, if I may ask the question, be the activity or action of the testosterone which he described?

A. I can't accept that statement without going through this thing here.

Q. I will hand it to you and, if you can, without taking too much time, locate it, I will appreciate it.

A. On what page?

Q. Page 1894 of the one I read from and it is marked on the margin with blue ink.

A. One would have to go through a great deal of this to see what exactly he is dealing with.

Q. Speaking generally, I wondered if that would

(Testimony of Warren Nelson, M.D.)

refresh your mind. I don't think it needs to be refreshed. But would it sound like a reasonable comparison to you?

A. In the case of what I think he is dealing with, the growth of pubic and axillary hair and change of the voice, that would be a reasonably comparative figure. In the case [114] of the effect on the testes, I don't know.

Q. I have another article here, "Testosterone Compounds in the Male, Clinical Indications and Methods of Administration," by Hans Lisser and Roberto Escamillo.

Mr. Elson: "The Urological and Cutaneous Review," Volume 46, February, 1942, and at page 92, under the heading of "Oral Methyl testosterone," it is said, "The discovery that the methyl ester of testosterone was effective by mouth constituted a great advance from the standpoint of simplicity and convenience. In our experience, five to eight times the parenteral dose is required orally to initiate definite subjective and objective improvement in severe cases of eunuchoidism." [115]

Would there be an inconsistency between the comparison that the two articles make?

A. Doctors Escamillo and Lisser were speaking in that connection of a comparison between the injected methyl testosterone and the oral testosterone?

Q. That the injected in their opinion would be five to eight times more potent.

A. Methyl testosterone? It is not a comparison

(Testimony of Warren Nelson, M.D.)

between testosterone propionate and methyl testosterone.

Q. It is not?

A. Not in that case that you showed me.

Q. Maybe I read it wrong.

A. It is a comparison between methyl testosterone injected and methyl testosterone taken orally.

Q. I see. The other one was three to five—or one-third to one-fifth, and would your testimony be that in the average case that that would be a fair comparison of the amount of methyl testosterone over and above testosterone propionate that would be necessary to obtain the same effects?

A. I assume you mean testosterone propionate given by injection?

Q. That is correct.

A. Those are figures that have been commonly published.

Mr. Elson: The purpose of this, your Honor, has been to [116] simply try and develop a comparison between the injected product and the one taken orally.

The Court: Yes.

A. May I say again here, however, that those figures do not relate, to the best of my knowledge, to the effect of the testosterone or methyl testosterone on the testes? They are on other structures affected by the male sex hormones.

Mr. Elson: I have no further questions.

(Testimony of Warren Nelson, M.D.)

Redirect Examination

By Mr. Danielson:

Q. What, Doctor, were those other structures of the body which you have just now referred to?

A. The voice, change in the pitch of the voice, pubic and axillary hair and face hair and body strength.

Q. But not the testes?

A. I tried to make that clear, that those studies did not apply to the testes, to the best of my knowledge.

Recross-Examination

By Mr. Elson:

Q. You wouldn't say, though, would you, Doctor, that the inhibitory effect—and this is what we are speaking of so far as the testes are concerned, are we not?

A. Yes.

Q. That the inhibitory effect, you wouldn't say, of methyl testosterone, taken 25 to 50 milligrams a day, would be equal over the same period of time to 25 milligrams of testosterone [117] propionate injected three to four times a week?

A. The methyl testosterone taken daily?

Q. Yes.

A. Compared with the testosterone propionate taken three to four times a week?

Q. Yes.

A. At 25-milligram levels in one case and 50 in the other?

(Testimony of Warren Nelson, M.D.)

Q. Yes.

A. That would be 75 against 350. Yes; certainly the orally ingested material would be 350 milligrams a week, equal to 75 milligrams of injected material. That is a difference of about five to one, isn't it?

Q. Just about. In other words, there one would be the equivalent of the other?

A. That would be true on the basis of the figures, which I think are representative.

Mr. Elson: I think that is all.

Redirect Examination

By Mr. Danielson:

Q. Another dosage of another form of testosterone, Doctor, assuming now the same situation, a normal man, and assuming that drug to be say a 5-milligram linguet of methyl testosterone, and the dosage was two tablets three times daily, which is six tablets daily, 5-milligram tablets of methyl testosterone as linguets, do you have an [118] opinion as to whether such an administration might result in sterility?

A. I have no data to base an opinion on there. I would simply have to say that methyl testosterone taken by linguets and, therefore, getting directly into the body circulation and not having to go through the digestive system, would be more likely to be effective at that level than double that amount taken orally.

Q. In other words, in your opinion, it would

(Testimony of Warren Nelson, M.D.)

have double the effect of an equal dosage swallowed or taken orally?

A. Yes, if you understand my affirmation of that being an opinion. I have no definite opinion in that regard.

Mr. Danielson: No further questions.

Mr. Elson: No further questions. [119]

* * *

Mr. Danielson: Dr. Macdonald.

IAN MACDONALD, M.D.

called as a witness on behalf of the government, being first duly sworn, testified as follows:

The Clerk: Your full name, Doctor?

The Witness: Ian Macdonald, M-a-c-d-o-n-a-l-d.
The "d" in the last name is not capitalized.

Direct Examination

By Mr. Danielson:

Q. Where do you live, Dr. Macdonald?

A. In Los Angeles.

Q. Of what school or schools are you a graduate?

A. Of McGill University, in 1928.

Q. And what degree was granted to you, please?

A. Doctor of Medicine.

Q. What postgraduate training have you had?

A. At the Montreal General Hospital I had three years of training in general surgery, a year as resident in pathology at the University of Michigan Hospital, and one year as Chief Resident

(Testimony of Ian Macdonald, M.D.)

Surgeon at the University of Toronto Hospital, after which I came out here and became a surgical pathologist at the Los Angeles County Hospital, and I am also doing general hospital work.

Q. Have you had some connection at the University of Southern California, Doctor?

A. Yes; I am Associate Professor of Surgery there and also coordinator of cancer teaching for the School of Medicine.

Q. Are you a member of any medical or other scientific societies?

A. Yes; I am a fellow of the American College of Surgeons and a member of the Cancer Committee of the American College of Surgeons; a member of the American Radium Society; a diplomate of the American Board of Radiology and Radiation Treatment; a member of the Los Angeles Surgical Society.

Q. Have you had any connection with the County Medical Association, Doctor?

A. Yes; at the moment I happen to be chairman of the Cancer Committee of the Los Angeles County Medical Association.

Q. What are the requirements, Doctor, for certification by the American Board of Radiology?

A. In my particular field the requirements are a minimum period of specialized training in the use of X-ray and radium in the treatment of cancer and related diseases and [123] related diseases and, also, a minimum period of experience and back-

(Testimony of Ian Macdonald, M.D.)

ground in the actual use of these agents in the treatment of tumors.

Q. What are those minimum periods, Doctor?

A. Three years of training and two years or more of actual experience.

Q. At least five years?

A. That is right.

Q. What is the function of the Cancer Committee of the American College of Surgeons, Doctor?

A. The Cancer Committee of that organization has been interested in developing information as to the proper method of treatment of various forms of cancer, and in determining what end result was obtained in the treatment of cancer. Of recent years one of the special interests of the Committee has been in the review and collection of information concerning new methods of treatment and their uses and dangers as well.

Q. Have you written and published any articles in medical or other scientific publications?

A. Yes, sir; I have.

Q. About how many have you published?

A. In excess of 20.

Q. Do some of these articles relate to cancer of the breast? [124]

A. Yes; over a third of these I have published has had to do with breast cancer.

Q. Are you engaged in any research of any nature at this time?

A. Yes; I am one of 45 collaborators throughout

(Testimony of Ian Macdonald, M.D.)

the country who are working under the auspices of the Committee on Therapeutic Trials of the American Medical Association.

Q. What is this, Doctor? Will you explain what that is?

A. It is a coordinated effort to try and evaluate the place and usefulness of male and female sex hormones, specifically in the treatment of breast cancer. By obtaining pooled information from a considerable number of investigators, the usefulness of these products can be determined with much greater saving of time than if one had to depend on individual investigators and individual institutions reporting their results, over a much longer period of time.

Q. Are you engaged in the practice of medicine?

A. Yes; I am.

Q. How long have you been so engaged?

A. Since 1932.

Q. Do you specialize in any branch?

A. Yes, sir.

Q. What is that?

A. I specialize in the treatment of cancer and related [125] diseases.

Q. As a surgeon?

A. As a surgeon and, also, using X-ray and radium treatment.

Q. What agents do you use in the treatment of cancer?

A. Surgery, X-ray and radium treatment, al-

(Testimony of Ian Macdonald, M.D.)

most exclusively; a few newer agents in a very limited number of patients.

Q. What would those agents be, just briefly?

A. A relevant example is the use of male and female sex hormones in cancer of the breast.

Q. Would alpha estradiol be one of the female sex hormones? A. Yes; it would.

Q. Have you treated cancer of the breast?

A. Yes, I have.

Q. About how many have you treated?

A. During the last 15 years, in excess of 1,000 cases.

Q. That is in the female human, is that right?

A. That is right.

Q. Have you conducted any studies of other cases of cancer of the breast?

A. Yes; six or seven years ago, I made a review and published an analysis of maybe 2,700 cases of breast cancer from the American College of Surgeons' files. [126]

Q. You have testified that you also use hormones in the treatment of breast cancer, is that correct?

A. In a very limited number of patients; yes.

Q. What hormone do you use in these cases?

A. Both male and female sex hormones.

Q. Why would you use these types of hormones?

A. Because there is an age-determined resistance to the hormone in women who have cancer of the breast. Women who are not yet at their change of life and whose ovaries are still functioning and producing hormones are treated by the male sex

(Testimony of Ian Macdonald, M.D.)

hormone with a beneficial effect in a very limited number of patients. On the other hand, in later life, after the so-called change of life, anywhere from five to ten years after the menopause, the female sex hormone is the agent of choice as far as a hormone is concerned.

Q. When you refer to the male hormones, do you refer to methyl testosterone, for example, or testosterone in any form?

A. Testosterone and androgenic hormones in general; methyl testosterone.

Q. Methyl testosterone is one of these?

A. Methyl testosterone happens to be a specific form of male sex hormone which is used for administration by mouth.

Q. What is the reason for this method of treatment? To refresh your recollection, what would be your reason for using a male hormone in treating a female human patient? [127]

A. Well, it has been established that, although we do not know the ultimate cause of cancer of the breast, certainly one of the necessary factors for its development is an excess quantity of female sex hormones in a younger woman. So, therefore, it seemed rational some years ago, in very advanced cases, who were not otherwise suitable for ordinary methods of treatment, to try the effect of the antagonistic opposite hormone, the male sex hormone, in younger women, with virulent forms of breast cancer. This was a natural development from information already known about the response of

(Testimony of Ian Macdonald, M.D.)

cancer of the prostate to female sex hormones. I think that is the answer that you desire.

Q. You have mentioned that at a certain age the female hormone was used. Will you elaborate on that a little bit?

A. Yes; the rationale for the use of female sex hormones in any cancer of the breast is far from clear because it seems unlikely that the agent which originally played an important part in the development of a form of cancer should be of any use in the treatment of such a tumor; but it was found in women past their menopause, and particularly in quite elderly women, the use of female sex hormones did have in a certain number of them a distinctly inhibitory effect upon the growth of the cancer. [128]

Q. (By Mr. Danielson): You previously referred to younger women. By younger women you mean what, Doctor?

A. I mean women in that physiological age period which includes before and up to the menopause.

Q. And by older women you mean women immediately after the menopause?

A. From the point of this discussion, it means women who have passed their menopause by five to ten years or more.

Q. Do you mean that a female hormone should not be used at all until a woman has passed her change of life, for a period of five to ten years?

A. No, I don't mean that. There is a wide field of usefulness for the female sex hormone with

(Testimony of Ian Macdonald, M.D.)

women who do not have cancer of the breast, who are at or near the menopause.

There are a number of situations which exist which are very well relieved by judicious use of the hormone, with competent medical supervision and repeated examination.

Q. Why would these repeated examinations be made, Doctor?

A. Because in certain women, the continued use of the female sex hormone may produce, or may I say that there is evidence to indicate that changes may occur in the breast and uterus which are, to say the least, undesirable, states of overgrowth can occur in the lining of the uterus, for example, and give rise to local overproduction of tissue in the lining [129] of the uterus, which constitute little benign tumors and are referred to as polyps, and either during or after the use of the hormone in such women, alarming bleeding may occur from the uterus. Those are distinct hazards in the use of female sex hormones.

Q. And what would be the danger as a result of this bleeding, what would be the result of such bleeding, in what respect would that be dangerous?

A. For one thing, it is difficult to tell whether such bleeding is a result of the developing growth, malignant or otherwise, in the uterus, or whether it is simply due to a disturbance of the lining of the uterus, from the use of the hormone.

Q. Now, in referring to female sex hormone, I

(Testimony of Ian Macdonald, M.D.)

gather you are referring to such products as alpha estradiol, is that correct? A. Yes.

Q. Would, specifically, a .5 milligram tablet of alpha estradiol be one of these?

A. It would.

Q. Would a .1 milligram tablet of chrystalline alpha estradiol be one of these?

A. Ordinarily, that dosage would not be very significant except in the small section of women who exhibit a very distinct sensitivity to the hormone. [130]

Q. Supposing a tablet of .1 milligram, tablet of chrystalline alpha estradiol were administered three times daily, what would the effect be of such a therapy?

A. That could produce the undesirable results which I described.

Q. Now, Doctor, have you treated or diagnosed cancer of the breast, the human breast, of the female, which in your opinion has been affected by the administration of female sex hormones?

The Witness: You refer now to young women?

Q. Yes.

A. Yes, I have in a very limited number of women certainly noticed some rather alarming signs in an existing cancer of the breast, because of the use of female sex hormone.

Q. (By Mr. Danielson): Doctor, you testified that you have diagnosed and treated such cases in which there was an affectation of this cancer or

(Testimony of Ian Macdonald, M.D.)

carcinoma. In what way were these cancers affected, in what manner?

A. These were young women with existing proved cancer of the breast in which the duration of the cancer and its approximate rate of growth could be determined within reasonable limits. After the administration of the female sex hormone, and within a short time thereafter, there occurred in each of these instances to which I refer, a very rapid and alarming increase in the growth pattern of this breast cancer. [131]

Q. What are your reasons for this opinion, Doctor?

A. The fact that this alarming increase in growth occurred shortly after the beginning of hormone treatment and that the rapidity and growth was entirely inconsistent with the known pattern of growth of the type of cancer of the breast and that there was no other factor to which it could be attributed.

Q. Was this cancer confined to the breast?

A. No. It was not. Not only in the local area where the tumor began in the breast, but also at other sites to which it had spread, did the same increase in growth occur after the female sex hormone was given.

Q. In other words, these remote growths were likewise affected, is that correct?

A. Yes, to such an extent that we now avoid completely the use of female sex hormone in breast cancer in women before their change of life.

(Testimony of Ian Macdonald, M.D.)

Q. Now, Doctor, on the basis of your professional training and education, experience, your studies of the literature, conferences and discussions with other doctors and your own research, do you feel that this phenomena that you have just described—do you have an opinion as to the consensus of medical opinion on that?

A. May I say, authoritative consensus from the literature and from those who have had wide experience is that there [132] is an extremely serious hazard in the use of the female sex hormone in such patients.

Q. (By Mr. Elson): Meaning what cases? Can we have it more specifically?

A. In patients who have a cancer of the breast and who are of this age period.

Mr. Elson: Who what?

A. Who are of this age period.

Q. (By Mr. Danielson): That is the premenopausal group, is that correct?

A. That is correct.

Q. Now, what is your opinion as to the effect of the amount of the female hormone administered in such cases, taking for example an administration of tablets of alpha estradiol containing .5 milligrams of the drug?

The Court: Just a minute. Is that in the manner which administration is made in the cases that the doctor refers to, orally, or otherwise?

Mr. Danielson: Well, that I don't know.

Q. (By the Court): Well, what was the hor-

(Testimony of Ian Macdonald, M.D.)

mone and in what form was it that was administered in these cases where it had a deleterious effect?

A. The hormone which we used was diethylstilbestrol, and it was given by mouth and not by injection.

Q. (By the Court): And in what dosage? [133]

A. Our dosage was five milligrams of strillbestrol anywhere from once to three times daily, in other words, a dosage of five to 15 milligrams per day.

Q. (By the Court): What prompted that treatment? Was it purely experimental?

A. No, sir. It was suggested by the relative amount of female sex hormone which had been found to be effective in cancer of the prostate. We now are finding that considerable less dosages are effective. Actually we are now carrying some elderly women with breast cancer and with good results on as little as 2.5 milligrams per day. It seems to have just as good an effect as the larger doses which we had been using.

Q. (By the Court): Well, in young women?

A. No, sir. We are using it only in elderly women, now.

Q. (By the Court): There is no amount in younger women under the menopause?

A. Under no circumstances, no, sir.

Q. (By the Court): And about how many cases were involved in a treatment where it had such a deleterious effect?

A. We only treated four cases, two of which exhibited this alarming and rapid increase in

(Testimony of Ian Macdonald, M.D.)

growth. That was enough to discourage us promptly, then.

Q. (By the Court): That was here locally?

A. That was here locally.

Q. (By the Court): And what if any similar experiences have been encountered elsewhere?

A. Similar experiences have been encountered by Nathanson in Boston, at the Massachusetts General, with whom I recently talked personally at Chicago and he has treated more women with breast cancer than any other single investigator in the country.

Still another investigator who has had the same experience is Essher at the Memorial Hospital in New York. In both of those places, they look now with extreme misgiving on the use of the hormone in young women with breast cancer.

Q. (By the Court): Have these men written on the subject?

A. No, sir. This information is recent, and it was obtained in definite form for the first time at a conference held in Chicago in April of this year at which the committee on therapeutic trials held a session of these 45 investigators from the country at large, so that the work which had been done and the results obtained and the hazards found to exist could be pooled and discussed, and it was at that meeting that information of this sort came to light in a really forceful fashion.

Q. (By the Court): Over what period in years back has the medical profession used male and fe-

(Testimony of Ian Macdonald, M.D.)

male sex hormones to any extent in the treatment of cancer, in any form? [135]

A. Well, Huggins at the University of Chicago was the first to use a hormone for any form of human cancer, when he began the use of the female sex hormone for cancer of the prostate. That as I remember began about 1937 or '38, which is my recollection.

The first effort at the use of hormone in cancer of the female breast in human was begun in a very tentative fashion in 1941, at the Memorial Hospital in New York.

To my knowledge, the first use of the female sex hormone in breast cancer did not occur until about 1944.

Q. (By the Court): Well, up to date, the standard treatment and the only one that is really known to the homeopathic medical profession is surgery, X-ray and reading?

A. Yes, sir. The very best results that are being obtained from hormone are not curative and there is no indication that it will ever be more than palliative or than just producing an inhibitory effect upon cancer of the breast, usually only for a period of months. In short, the results of the use of hormone in breast cancer have not been nearly as good as the results of hormone control of cancer of the prostate. And in point of fact, both the male and female sex hormone apparently constitutes a distinct hazard in certain women, in that they both

(Testimony of Ian Macdonald, M.D.)

produce an acceleration of growth rather than a control of the tumor. [136]

* * *

Q. (By Mr. Danielson): Doctor, to clarify a couple of points, when you refer to the use of the female hormone in women with favorable results, you are referring to the postmenopausal group, is that not correct?

A. Strictly. and the older the woman, the more apt she is to obtain a good result.

Q. And by postmenopausal you mean a period starting five to ten years after the menopause, is that not correct?

A. That is the definition as set up in April of this year by the Committee, at least five, preferably ten years after the menopause.

Q. And when you speak of using the male hormone or testosterone in a female, with favorable results, you are referring only to the group in the premenopausal age, is that not correct?

A. Largely so, yes.

Mr. Elson: May I have the last question and answer read, please?

(Record read.)

The Witness: That should be qualified, I think, by saying that the use of the male sex hormone in elderly women [137] does not offer the same hazard as the use of the female sex hormone does in younger women, if I have made that clear.

In short, the disadvantage of the male sex hor-

(Testimony of Ian Macdonald, M.D.)

mone in patients who have cancer of the breast and who are elderly is that it is apt to be ineffective rather than dangerous.

Q. (By Mr. Danielson): And conversely, the use of the female sex hormone in the younger women would have what result?

A. Not only almost always ineffective but according to our present information, in probably half of them there is a distinct and serious hazard in this increase in growth.

Q. And, Doctor, when you are referring to this hazardous use or the dangerous effect of the female hormone, would your opinion apply to dosages of .5 milligrams of alpha estradiol administered daily?

A. That I cannot say with certainty, not having used this particular form of the hormone, but I believe on a relative basis, that for that dosage, when continued for a long enough period of time, that these results could occur.

Q. Do you have information, Doctor—do you know the incidence of breast cancer, female human breast cancer, in the United States?

A. Yes. In the U. S. registration area, during the last several years, at any given time there are approximately 80,000 women who have cancer of the breasts, and there are [138] annually 18,000 deaths, per year, from breast cancer.

Q. How are these cancers diagnosed in the early stages, Doctor?

A. Only by surgical removal of a lump on the breast and microscopic proof of the presence of cancer.

(Testimony of Ian Macdonald, M.D.)

Q. That requires special training, does it not, sir?

A. It requires competent surgical service, yes.

Q. Are there any subjective symptoms of breast cancer which would enable a lay person to properly diagnose that?

A. Only one, the presence of a lump in the breast.

Q. And is that a certain diagnosis?

A. Oh, no. A lump in the breast may be 27 other things besides cancer.

Q. Can this lump in the breast—would this lump in the breast, could it be a cancer in the breast too small to diagnose by touch?

A. Certainly.

Q. By feel? A. Certainly.

Q. And would such a cancer likewise be affected by the use of the hormones?

A. Yes, indeed.

Q. Well, Doctor, is it possible for a female human to have a carcinoma of the breast without knowing it? A. Oh, surely. [139]

Q. And without being able to determine it by subjective symptoms?

A. Certainly. Many early cancers of the breast are indicated on routine physical examination, with the woman unaware of the presence of any sort of process in the breast whatever.

Mr. Danielson: No further questions.

The Court: Pardon me a minute before you cross-examine.

Q. Will you tell me what this alpha estradiol drug hormone is, what is it? I don't understand it.

(Testimony of Ian Macdonald, M.D.)

A. The female sex hormones referred to in generic fashion as the estrogenic hormones are considerable in number with the development of a number of different forms of the hormone which differ chemically in some minor respects and some of them are acquired from natural sources such as the blood or urine of pregnant animals. Others are made synthetically in the laboratory.

Q. (By the Court): Why from pregnant animals?

A. Because a pregnant animal has such an excess of the hormone circulating in the blood that it can be recovered in enough quantities.

Q. (By the Court): And that is the reason——

A. Yes, sir.

Q. ——for the cause of the source for the laboratory?

A. Yes. The main portion of the female sex [140] hormone now used, however, is synthetic because it is made quickly and cheaply in the laboratory and has the same effect on tissues in the female that the so-called natural sources of estrogenic hormone accomplish.

Q. (By the Court): Well, synthetically, in what manner, generally speaking?

A. By starving with several chemicals—I know chemistry, you Honor. By diethylstrillbestrol, which is made in a laboratory simply by the chemical fusion of several other chemicals, which when united produce complex molecular changes, estrogenic in its qualities.

The Court: You may go ahead.

(Testimony of Ian Macdonald, M.D.)

Cross-Examination

By Mr. Elson:

Q. Is it your opinion, Doctor, that cancer of the breast is caused by estrogen?

A. No. The ultimate cause of cancer of the breast we do not know, but there are certain necessary preliminary factors which must be present in order that cancer of the breast may develop in a woman, and estrogenic hormone is one of these background causes of breast cancer.

Q. But there has been no definite proof as yet, I take it, that estrogen has been a cause of cancer of the breast?

A. You mean artificially administered estrogen, or [141] natural estrogens within the patient?

Q. Well, let us take natural estrogens within the patient.

A. That is established.

Q. It has been?

A. It is authoritative opinion that that is a necessary factor preceding the development of breast cancer.

Q. You mean a necessary factor in that there must be some estrogen there?

A. There must be a certain amount of circulating estrogen over a long period of years in the woman's life, within herself, in order that breast cancer may develop.

Q. Well, do you find in your experience that the incidence of breast cancer is greater with women who have had no children, or women who have had

(Testimony of Ian Macdonald, M.D.)

some children or women who have had a lot of children, or just what?

A. I have statistical information on that subject. The incidence of cancer of the breast is distinctly greater in those women who have not borne children, or who having borne children have failed to nurse them at the breast.

Q. Now, Doctor, is it true that a pregnant woman produces during pregnancy considerable more estrogen than a woman who is not pregnant?

A. That is true.

Q. And the amount of estrogen that the woman produces [142] increases during the period of pregnancy?

A. That is true.

Q. Now, coming down to a practical everyday matter, isn't it common and a general thing for many women who have gone to, say, their general practitioner and who have received shots as we say of estrogen or estrogenic substance and thereafter have been put, if I may say, on a maintenance dose of tablets taken orally on prescription, do thereafter and repeatedly have that prescription refilled without having another prescription issued? Do you get what I mean?

The Witness: Yes.

Mr. Elson: Isn't that common?

A. That is common.

Q. (By Mr. Elson): Has it been your experience that it is the common practice of general practitioners to have patients who complain of symptoms that would lead the ordinary doctor to believe

(Testimony of Ian Macdonald, M.D.)

that estrogen would be helpful to have the woman examined to see whether or not a cancer of the breast was present, before prescribing estrogen?

A. Oh, any reasonably competent physician does an adequate physical examination before the use of estrogenic hormone.

Q. I didn't mean that. I do not dispute that, but let us take it here, the information alleges early and incipient cancer of the breast, cervix and uterus. Do you think that [143] it is possible for the average doctor to diagnose an incipient cancer of the breast, keeping in mind the meaning of the word incipient?

A. It is possible for him to detect an abnormal area of thickening or a very small actual lump in the breast which requires removal and microscopic examination.

Q. Would you say that was in its incipency, just in the beginning?

A. The microscope may prove it to be so.

Q. That might be true under microscopic examination but would you say that would be the usual practice of the general practitioner, keeping in mind here that we are concerned with a carcinoma which is in its early and incipient stage? That is the language that has been chosen in the information, the language being that 5/10 of a milligram of estradiol may accelerate the growth of an early and incipient carcinoma. That is what we are talking about. Do you think that the average general practitioner, to whom a woman went, would be able to diagnose an early and incipient cancer of the breast?

(Testimony of Ian Macdonald, M.D.)

A. I could only say that there are certain states in the breast which precede the actual development of cancer and they are accompanied by a detectable lump or thickening in a part of the breast, which would be apparent to any well-trained general physician and would be an indication to him of surgical removal of that area of the breast.

Q. By the time it had reached that stage, would you say it was in its incipency? [145]

A. No; it is generally an established cancer.

Q. Isn't it true that, when the cancer has reached that stage, the woman is conscious of something there in her breast?

A. Many such women are not conscious of anything in the breast at all.

Q. Aren't many women very fearful of the possibility that something that might be a little bit out of the ordinary in their breast might indicate a cancer?

A. A certain number of the female population is in that frame of mind.

Q. Don't you think the vast majority of them are conscious of that possibility?

A. No; I certainly don't.

Q. I take it that neither you nor anyone else knows the cause of cancer of the breast?

A. No; the ultimate or the trigger mechanism that actually sets off the cancer we don't know the nature of.

Q. And it logically follows then, of course, that

(Testimony of Ian Macdonald, M.D.)

you are unable to say that estrogen or that anything else is the cause of it?

A. That is hardly accurate. I again return to the fact that in the background of a human breast cancer estrogenic hormone is of importance. Witness the fact that in women who have, for one reason or another, been castrated in [146] early life, and by "early life" I mean their late twenties or early thirties, where they are castrated surgically or by X-ray treatment, the incidence of breast cancer in those women in later life is about 1/20th of the female population which comes up to a normal physiologic change of life.

Q. You know, do you not, that great quantities of estrogen or estrogenic substance are sold by manufacturers in this country? A. Yes, sir.

Q. Am I correct in saying that the principal source, manufacturing source, of that would be the Ciba Pharmaceutical Corporation and Roche-Organon?

A. Yes; they manufacture a good share of it.

Q. Wouldn't it be fair to say that the number of packages of that product that are sold in the United States during the year would run into the hundreds of thousands?

A. I assume it would.

Q. By the way, does a woman produce estrogen after she has passed the menopause?

A. Yes; she does.

Q. In any great quantity ?

A. In a considerably diminished quantity, ap-

(Testimony of Ian Macdonald, M.D.)

parently from the adrenal glands rather than from the ovaries.

Q. Do I understand you to say the incidence of breast cancer occurs more in the pre-menopausal woman or the [147] post-menopausal woman?

A. The peak incidence of breast cancer occurs at and immediately after the menopause. The ages of 40 to 55 account for the time of greatest incidence of breast cancer.

Mr. Elson: The doctor didn't testify to anything other than cancer of the breast, did he?

Mr. Neukom: No; he didn't.

Q. (By Mr. Elson): You spoke of Dr. Nathanson, Ira Nathanson. A. Yes, sir.

Q. Are you familiar with the paper that he wrote that appears in Volume I, Recent Progress in Hormone Research? A. No; I am not.

Mr. Neukom: Show it to him.

A. I am familiar with the journal but not with that paper.

Q. (By Mr. Elson): You consider Dr. Nathanson, I take it from your direct testimony, to be an authority on the subject of breast cancer?

A. Yes; I do.

Q. I am going to read you a statement that he makes under the heading of "Conclusions," on page 281, and ask you if you agree with the statements that he has made——

Mr. Danielson: Your Honor, for the sake of the record, may we have the date of this publication?

Mr. Elson: Oh, yes. I beg your pardon. The

(Testimony of Ian Macdonald, M.D.)

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(Testimony of Ian Macdonald, M.D.)

parently from the adrenal glands rather than from the ovaries.

Q. Do I understand you to say the incidence of breast cancer occurs more in the pre-menopausal woman or the [147] post-menopausal woman?

A. The peak incidence of breast cancer occurs at and immediately after the menopause. The ages of 40 to 55 account for the time of greatest incidence of breast cancer.

Mr. Elson: The doctor didn't testify to anything other than cancer of the breast, did he?

Mr. Neukom: No; he didn't.

Q. (By Mr. Elson): You spoke of Dr. Nathanson, Ira Nathanson. A. Yes, sir.

Q. Are you familiar with the paper that he wrote that appears in Volume I, Recent Progress in Hormone Research? A. No; I am not.

Mr. Neukom: Show it to him.

A. I am familiar with the journal but not with that paper.

Q. (By Mr. Elson): You consider Dr. Nathanson, I take it from your direct testimony, to be an authority on the subject of breast cancer?

A. Yes; I do.

Q. I am going to read you a statement that he makes under the heading of "Conclusions," on page 281, and ask you if you agree with the statements that he has made——

Mr. Danielson: Your Honor, for the sake of the record, may we have the date of this publication?

Mr. Elson: Oh, yes. I beg your pardon. The

(Testimony of Ian Macdonald, M.D.)

publication is entitled "Recent Progress in Hormone Research," Proceedings of the Laurentian Hormone Conference, Volume 1, and the date is 1947, and published by the Academic Press, Inc., of New York.

Q. On page 281, Dr. Nathanson says, under the heading of "Conclusions," "A considerable number of data bearing on the relation of the endocrine hormone to tumors have been accumulated. The administration of sex hormones to experimental animals has resulted in the production and augmentation and the inhibition of benign and malignant tumors. These are really two definite types of tumors in different species as well as certain strains in any one species of animal. Thus, there are other factors that determine the reaction of a tissue to a hormonal stimulus and the susceptibility of an animal to the induction of neoplasm. It is difficult to interpret these facts in terms of human cancer. Nevertheless, they are of extreme importance in the study of the origin and growth of cancer in general."

Would you agree with that statement?

A. I would agree with that and say also that it bears no relevance to what was discussed here this morning. I have made no claim that in the human family estrogen hormone has anything to do with the production of cancer. I would say, first, that inherent in the woman herself there must be an intrinsic [149] production of her own hormone to lay the background for breast cancer, and that in

(Testimony of Ian Macdonald, M.D.)

a woman who has developed a cancer of the breast the female sex hormone may then accelerate an existing cancer of the breast. I, too, don't believe that the use of female sex hormones, given in therapeutic doses, has ever produced a cancer of the breast.

Q. Let's leave the relevancy of anything that you say or that I say for the court to determine.

A. I am sorry you have introduced that. There seems to be a sharp division of ideas here.

Q. Are you familiar with a book entitled "Endocrinology of Neoplastic Diseases—A Symposium," published by Oxford Medical Publications, 1947?

A. Yes, sir. I happen to own one.

Q. One of these volumes? A. Yes, sir.

Q. The particular chapter that I have reference to is again by Dr. Nathanson. It is chapter 6, page 138, entitled "The Relationship of Hormones to Diseases of the Breast," by Ira T. Nathanson, M.S., M.D., Boston, Massachusetts. On page 165 he states: "Attempts have been made to influence the course of cancer of the breast by the administration of hormones. It was found that carcinogenic and hydrocarbons possess the property of retarding the growth of normal and malignant tissues in experimental animals. Since some of these [150] compounds are similar in chemical structure to the estrogens, the latter are now the subject of investigation relating to cancer of the breast. Several of these substances have been used. Observations thus far indicate that they may cause a definite, although

(Testimony of Ian Macdonald, M.D.)

apparently temporary, partial regression of the primary tumor in some patients.”

Have you had any similar experience such as Dr. Nathanson related there, Dr. Macdonald?

A. No; I haven't. And this sort of investigating work can be profoundly modified by new experience.

Q. How is that?

A. These conclusions may produce—such early investigative work can be profoundly modified by subsequent experience and, according to my recent contact with Dr. Nathanson in Chicago two months ago, he, himself, has had reason to modify his own views about the use of female sex hormones in women with breast cancer. He, too, has developed I shall say a very reserved attitude toward it.

Q. That isn't unusual, is it, in the case of investigators and research men in the field of medicine, that, within a short period of time after they have arrived at what might appear to be a conclusion on a subject, they may have considerable doubts as to the validity of their former opinion?

A. Yes, sir. That is always the danger of sticking your neck out in print. [151]

Mr. Elson: I don't have any other questions. Well, wait just a moment. Did I understand you to say on direct testimony that—well, Mr. Sturzenacker has just called it to my attention that you made a statement on your direct testimony concerning the amount of alpha estradiol that, in your opinion, would be dangerous in causing the acceleration of the growth of a breast cancer. Did you?

(Testimony of Ian Macdonald, M.D.)

A. Yes, sir; I did.

Q. And what was that?

A. Well, translated, it is that any amount of any form of female sex hormone which is capable of producing a physiologic effect in a woman may adversely affect the course of an existing cancer of the breast.

Q. And, in your opinion, would such an amount be 5/10 of a milligram per day?

A. That can produce a physiologic effect; yes.

Q. Now, let's get back to the incipient breast cancer. Let's just assume for the purposes of the discussion here that an incipient cancer of the breast is diagnosible, that is, you can find it. Is there any clinical evidence with which you are familiar that 5/10 of a milligram of alpha estradiol will cause the acceleration of such a cancer?

A. No, there is no actual specific proof of which I am aware but the theoretic hazard of its possibility is such that I would want to avoid it at all cost. [152]

Q. Isn't it true that the opinion that you hold in that respect might, by the same token, change a year from now, as Dr. Nathanson's opinion on this subject has changed here in April?

A. Yes; no individual at the present time has absolute knowledge concerning the question which you have just propounded.

Q. Did I understand you to say that you consider stilboestrol to have any effect, possible effect, in accelerating the growth of a breast cancer?

(Testimony of Ian Macdonald, M.D.)

A. I sure do.

Q. Do you know whether or not stilboestrol is on the dangerous drug list in California?

A. Yes; it requires a prescription.

Q. And isn't it a fact that alpha estradiol is not?

A. For some reason, it is not.

Mr. Elson: That is all.

Redirect Examination

By Mr. Danielson:

Q. Doctor, you just mentioned that you believe that alpha estradiol is not on the dangerous drug list in California. Do you have an opinion as to whether it should be?

A. I certainly think it should be. If stilboestrol is on such a list, so should alpha estradiol be.

Q. As to the dosages of alpha estradiol which can produce [153] a physiological result, in your opinion, could a dosage of .1 milligram of crystalline alpha estradiol three times daily produce such a result?

A. I believe it could. I personally have not used alpha estradiol but, from my knowledge of its potency, I believe that in a substantial number of women it could do so.

Q. That would be your opinion?

A. Yes, sir.

Q. You have mentioned that the incidence of breast cancer in a human female is greater in women who have never been pregnant than in those who have. Can you explain that, Doctor?

(Testimony of Ian Macdonald, M.D.)

A. Only in terms of the fact that the normal function of the breast should be that of lactation on at least several occasions during a woman's life, and there is both laboratory and experimental evidence and also extremely sound evidence, concerning cancer of the breast in the human female, that the failure of the breast to perform its expected physiologic function produces disturbances in the tissue of the breast as a result of prolonged years of bombarding of the breast tissue by the hormones to which it is subject from the ovary, without the breast going on to perform its proper function in a woman's life. As a result of that long continued stimulation of the breast, without proper function, certain changes are set up which eventually may lead to the development of cancer. [154]

Q. You have mentioned, Doctor, that during hormone therapy of pre-menopausal women there is not only a preliminary examination but periodic examinations during the course of the treatment. What is the purpose of that, Doctor?

A. The purpose of it should be to determine that there have not occurred some of the local overgrowths of tissue in the so-called target organs on which female sex hormone has its effect. If these states of tissue overgrowth have developed, it should be the signal for the discontinuance of the hormone.

Q. The treatment is contra-indicated once such thickenings or lumps appear, is that correct?

A. Usually; yes.

(Testimony of Ian Macdonald, M.D.)

Q. Is a carcinoma or cancer of the human female breast detectable at an early enough stage so that treatment will bring favorable results?

A. Oh, surely.

Q. If such an early detected cancer exists or were accelerated in its growth, could that progress get beyond control?

A. Over a certain period of time; yes.

Q. Thank you. No further questions.

Recross-Examination

By Mr. Elson:

Q. Have you found in the majority of instances you are able to control the growth of a breast [155] cancer so that the patient lives the normal span of life, as she would if she didn't have it?

A. The control of breast cancer depends entirely upon the stage to which the growth has developed and its extension to other sites at the time of surgical treatment.

Q. Do you think that an increase in the metabolic rate of the patient would have any influence on the growth of cancer?

A. There is no evidence to support that idea that I know of.

Mr. Elson: That is all.

Mr. Danielson: No further questions.

No. 12665

United States
Court of Appeals
for the Ninth Circuit.

UNITED STATES OF AMERICA,
Appellant,

vs.

EL - O - PATHIC PHARMACY, MARTIN A.
CLEMENS, HUDSON PRODUCTS COM-
PANY, MAYWOOD PHARMACAL COM-
PANY and ALLEN H. PARKINSON,
Appellees.

Transcript of Record
In Two Volumes
Volume II
(Pages 463 to 1014)

Appeal from the United States District Court,
Southern District of California,
Central Division.

FILED

DEC - 9 1950

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Appeal from the United States District Court,
Southern District of California,
Central Division.

Mr. Danielson: Dr. Heckel, please.

NORRIS J. HECKEL, M.D.

called as a witness by the government, being first duly sworn, testified as follows:

The Clerk: Your full name, Doctor?

A. Norris J. Heckel, H-e-c-k-e-l.

Direct Examination

By Mr. Danielson:

Q. What is your address, Dr. Heckel?

A. 122 South Michigan, Chicago, Illinois.

Q. What schools did you attend and what degrees did you [156] receive?

A. I received an A.B. degree from the University of Iowa and the M.D. degree from the University of Chicago.

Q. When did you receive this M.D. degree, Doctor? A. 1927.

Q. What post-graduate training have you had, if any?

A. I studied in Vienna, Hamburg and Paris in 1929 and also took some post-graduate courses in neurology at the Presbyterian Hospital in Chicago.

Q. Of what medical and scientific societies are you a member, Doctor? [157]

A. I am a Diplomat of the Society of Urology, a Fellow of the American College of Surgeons, member of the Association of Genito-Urinary Surgeons, Clinical Society of Genito-Urinary Surgeons, Western Surgical Association, American Urology

(Testimony of Norris J. Heckel, M.D.)

Association, North Central Urology Association, a member of the Society for the Study of Internal Secretions.

Q. What hospital appointments do you hold, Doctor?

A. I am Chairman of the Department of Urology at the Presbyterian Hospital in Chicago, and attending neurological surgeon at the Ravenswood Hospital, and on the advisory board of the Intensive Treatment Center in Chicago.

Q. What teaching appointments do you hold, if any, Doctor?

A. Professor of Urology at the University of Illinois College of Medicine.

Q. Are you now engaged actively in the practice of medicine, privately in practice?

A. In the practice of urology.

Q. What is urology, Doctor?

A. It is the study and treatment of the genito-urinary diseases, or diseases of the genito-urinary system in men and of the urinary organs in the females.

Q. It does not include the genital system of the female?

A. That is right. [158]

Q. Have you had occasion to write or publish any articles on medical or scientific subjects?

A. Yes, I have.

Q. About how many such articles?

A. In the neighborhood of 80, I would say.

Q. Have some or any of these dealt with hormones and their effects?

A. Yes, sir.

(Testimony of Norris J. Heckel, M.D.)

Q. Have any of these articles related to the effects of the male hormone, testosterone?

A. Yes, sir.

Q. And what were the sources of the information which you included in your articles, generally?

A. They were the results of investigations, from the use of testosterone upon the genital organs of man.

Q. Do you make use of testosterone, the male hormone, in your practice?

A. Yes, sir.

Q. Generally speaking, under what conditions do you use testosterone in your practice?

A. In urology, we use it only for the treatment of men that have a deficiency of male sex hormone.

Q. Under what circumstances do you find that there is a deficiency of the male hormone?

A. Of the male hormone in man? [159]

Q. Yes.

A. Diseases, would you like to have?

Q. Yes, under what classes of cases is there such a deficiency?

A. Well, endocrine disturbances, which is best illustrated in eunuchism.

Q. And what is eunuchism?

A. Eunuchism is a disease characterized by a deficiency of male sex hormone, in which the body is not able to manufacture this hormone. It really is characterized by a female-male, that is, these men have the characteristics of a female; they have no beard, they have hypogonadism, hypogenitalism, a

(Testimony of Norris J. Heckel, M.D.)

high pitched voice; their extremities are out of proportion to their trunk; no beard.

Q. In your statement hypogonadism, for instance, what is the meaning of the prefix hypo?

A. Hpyo, that means below normal.

Q. And gonadism?

A. Gonad means testes. Gonad and testes are synonymous.

Q. It refers to the gland, in other words, the gonad? A. That is right.

Q. Now, are there any other types of persons who have a male hormone deficiency other than the eunuchoid?

A. Oh, yes. There are those unfortunate people that for some reason or other might have had a disease that would [160] have destroyed their testes. A young boy, for instance, that has had mumps and as a result of the mumps has developed an orchitis in which there was a destruction of part of or most of the testes.

Q. Orchitis means what, Doctor?

A. That means an inflammation of the testes. There are injuries to the testes as a result of accidents, failure of the pituitary gland, for instance, in which there is a lack of development of the testes, undescended testes, those are a few of the diseases that might be associated with a testicular deficiency, of a male sex hormone deficiency.

Q. In an instance of an actual castration, this would likewise be true, I assume?

A. Oh, yes.

(Testimony of Norris J. Heckel, M.D.)

Q. In all of those cases, Doctor, is it true that the male hormone is used, is administered to replace that which the body has failed to provide?

A. That is right.

Q. What are some generally of the symptoms of this male hormone deficiency?

A. Symptoms: Well, a patient may be impotent, for instance. It is a very common symptom. Outside of that, he has the general symptoms, he fatigues easily, he tires easily for instance.

Q. Now, Doctor, you are familiar with the symptoms in [161] which male hormone deficiency is indicated, in which male hormone therapy is indicated?

A. I think I am, yes.

Q. Now, Doctor, on the basis of your education, professional training and experience, your study of the literature, your research, your conferences and discussions with other doctors, in short, on the basis of the sum of your professional knowledge, do you have an opinion as to whether the use of methyl testosterone would stimulate the growth and development of the sex organs and the male sex characteristic such as distribution of hair, muscular development and depth of voice? [162]

* * *

The Court: I think the witness may answer and should answer that question. At this stage of the evidence it is quite difficult for me to pass on whether it is material or competent in the case, and

(Testimony of Norris J. Heckel, M.D.)

subject to a later motion to strike, I will admit it and overrule the objection. [164]

* * *

A. The answer is that it would, methyl testosterone would.

Q. (By Mr. Danielson): Under what circumstances?

A. An individual that has a deficiency of testosterone or male sex hormone, as a matter of fact that is best illustrated in the eunuchoid individual in which you can make these individuals perfectly normal men by the use of this material.

Q. Now, do you have an opinion as to the incidence, the average incidence of such phenomena, of the eunuchoids, the persons to whom you have referred?

A. To the best of my knowledge, there are no available statistics. I would say that it is not too common a disease. I would classify it in comparison to other diseases as rather rare, perhaps.

Q. Could you give an opinion in round numbers as to percentage of incidence?

Mr. Elson: Isn't this immaterial, your Honor? We are concerned not with just the subject of eunuchoids. We are talking here of a male hormone deficiency and whether or not the symptoms alleged in the complaint will be relieved by an administration of it. Now, true, one of the symptoms of a male hormone deficiency may be that a person is a eunuchoid or he may be suffering from a number of conditions that the Doctor has just mentioned,

(Testimony of Norris J. Heckel, M.D.)

but, it seems to me that that is [165] immaterial to the question that is in issue here.

Mr. Danielson: Your Honor, this may be a little remote, but I believe it would be of great assistance to the court and to all parties concerned to allow the Doctor to express his opinion, if any, on the subject. The incidence of the deficiencies certainly has a bearing, it shows how few people might have this symptom. It has a bearing on the efficacy of this therapy.

The Court: That is the symptom of a deficiency?

Mr. Elson: That is correct.

The Court: The incidence of symptoms of a deficiency, yes, you may answer that.

(Pending question read.)

A. This would be purely a guess. I would say perhaps one I believe out of two or three hundred might have some evidence of endocrine disturbance.

The Court: Will you confine that now to youth? You say "boy" which indicates that you have in mind use in earlier years. I thought at the time one of the objections was made to the question was the relative number of people who might be afflicted that way. Of course, you mean males, counsel?

Mr. Danielson: Yes, males.

The Court: You mean throughout the entire population in this country, that is, the United States, or in some [166] sections of it?

Mr. Danielson: In any age group.

The Court: It is conceivable to me that it might vary between North and South, as in hot and cold

(Testimony of Norris J. Heckel, M.D.)

climates, high and low altitudes and something of that kind.

Mr. Danielson: I would say throughout the country in any age group.

The Court: Yes. Now, in any age group?

A. I would still say that the figures that I gave would be as close as I could come approximately. I don't know of anyone that has presented figures as to that. They may have. [167]

Q. (By Mr. Danielson): Doctor, are those symptoms, the symptoms indicated in that question, the symptoms of undeveloped sex organs and lack of hair and lack of muscular development and high-pitched voice, are they or could they be the symptoms of any other disease?

The Witness: I beg your pardon?

Q. (Mr. Elson, continuing): Are they the symptoms of any disease other than male hormone deficiency?

A. Those symptoms, they would be—those are really not symptoms. Those are findings that are associated with testicular deficiency.

Q. (By the Court): Arising from any source, naturally, from birth, or by accident and what not?

A. Yes, from accident, birth.

Q. (By the Court): Do you think about 2 per cent?

A. Well, I said one out of two or three hundred, I mean with some endocrine disturbance.

The Court: Oh, I got it wrong.

(Testimony of Norris J. Heckel, M.D.)

Q. (By Mr. Danielson): Now, Doctor, on the basis again of the sum of your knowledge, of your medical and scientific knowledge of hormones and their use and endocrine disturbances, do you have an opinion as to whether hormone therapy would in a man in his later 40s correct the lack of sexual power and impotence?

A. It wouldn't correct the impotence, if this impotence [168] were not due to a deficiency of male sex hormone.

Q. It would be, again, only in the event that there is a deficiency? A. That is right.

Q. Again, on the basis of the sum of your medical and scientific knowledge relative to endocrine disturbances and hormones, do you have an opinion as to whether male hormone therapy, methyl testosterone in a man in his late 40s would relieve and postpone the many conditions associated with middle age and would improve the sense of well-being?

Mr. Elson: Your Honor, I don't want to make an objection every time a question is asked, but may it be understood that there will be an objection or that there is an objection made to each one of the questions along this line involving these symptoms that I refer to in the information, in the first portion of the charge?

Mr. Danielson: That would be agreeable to the government, if it is agreeable to the court. [169]

(Testimony of Norris J. Heckel, M.D.)

The Court: I was going to suggest to Mr. Danielson that you might consider reframing the question.

Mr. Danielson: Yes, your Honor, I am perfectly agreeable to doing so.

Q. Doctor, on the basis of the sum of your knowledge, your medical and scientific knowledge relative to endocrine disturbances and the use of hormone therapy, do you have an opinion as to whether the administration of methyl testosterone would correct lack of sexual power and impotence in a person who has a male hormone deficiency?

A. It would.

Q. It would? A. That is right.

Q. Assuming the same educational background, experience and sum of your knowledge, would male hormone therapy relieve [172] and postpone the many conditions associated with middle age and improve the sense of well-being in a person who is suffering from a male hormone deficiency?

A. It would.

Q. (By the Court): Well, now, if you don't mind the interruption. But, it is my business to ascertain as near to the facts and the truth as I can. I would like to know from the witness, then, what would be the effect. Firstly, do males of that age generally lack somewhat in deficiency of this hormone?

A. It is my opinion they do not.

Q. (By the Court): They do not?

A. That is right.

(Testimony of Norris J. Heckel, M.D.)

Mr. Danielson: If your Honor please, I will lead into that.

Q. (By the Court): The next thing I want to know, then, is assuming that they have the normal amount, what, if you know, would be the effect on them as to an increased stimulation?

A. It would do two things. First, it would destroy the seminiferous tubules of the testes, and, two, it would aggravate the growth and dissemination of prostatic cancer.

The Court: Well, now, you take your witness again.

Mr. Danielson: Yes, your Honor. Thank you.

Q. Now, again assuming, Doctor, your own medical and [173] scientific knowledge and experience, do you have an opinion as to whether any man who has a male hormone deficiency, methyl testosterone therapy would constitute an adequate treatment for flushes, sweats and chills, impaired memory, inability to concentrate on activities and tendency to avoid them, nervousness, depression, general weakness and lack of physical strength?

A. It would have no effect unless those symptoms were associated with a testicular deficiency. But there are many diseases that would produce those symptoms.

Q. And again, Doctor, assuming your medical and scientific experience, education and training, your knowledge of endocrinology and male hormones, do you have an opinion as to whether with a man who has a male hormone deficiency methyl testosterone

therapy would result in improving physical and (Testimony of Norris J. Heckel, M.D.) mental work and would exert a tonic action resulting in renewed vigor?

A. It would, if he had a testicular deficiency.

Q. And again, assuming your medical and scientific training and knowledge, the sum of your knowledge of edocrinology in hormones, in any man who has a male hormone deficiency, would methyl testosterone therapy impart a better attitude towards social life and cause nervousness, exhaustion and melancholy to disappear?

A. It would. [174]

Q. Are these symptoms also the symptoms of any other diseases or condition? A. Oh, yes.

Mr. Elson: I object to that as immaterial.

The Witness: There is hyperthyrodism——

The Court: Just a moment, please.

Mr. Elson: Doctor, I made an objection.

The Witness: Oh, pardon me.

Mr. Elson: Object to the question on the grounds it is incompetent, irrelevant and immaterial to any issue in the case. We are talking about male hormone deficiencies. That is what the government has pleaded and it seems to me that we are getting into a field that is far removed from the subject under discussion here. That would open the door to going into that on cross-examination, your Honor, and when we wind up, it has proved nothing.

The Court: Reporter, will you read that question again.

(Question read by the reporter.)

(Testimony of Norris J. Heckel, M.D.)

The Court: That is, you mean other than a deficiency in this male hormone?

Mr. Danielson: That is correct. Are there any other pathological conditions which would have these symptoms?

The Court: Oh, well, I would say that that is a matter of common knowledge, whether they would have, but I will hear the answer. [175]

A. Many other diseases will produce those symptoms.

Q. (By Mr. Danielson): There are many other conditions? A. That is right.

Q. Now, Doctor, how is male hormone deficiency in any person determined?

A. Determined by, first, a careful history, No. 2, a careful physical examination and No. 3, there are some laboratory tests that will aid in diagnosis, such as the estimation of 17 kitosteroids in the urine.

The Court: The absence?

The Witness: The absence——

The Court: That is, in number, under 17?

A. No. That is just the name of that particular androgen is all. [176]

Q. (By Mr. Danielson): 17 is a part of that name? A. Just a name, yes.

Q. Is that a male sex hormone?

A. It is an androgen, and an androgen is another form of male sex hormone.

Q. What other methods, if any, are there for determining whether or not the male hormone deficiency exists?

(Testimony of Norris J. Heckel, M.D.)

A. The estimation of the excretion of gonadotropins also in the urine. But those laboratory procedures usually supplement or aid other physical findings.

Q. Do those examinations require special training, Doctor? A. That is right.

Q. Are there any subjective symptoms which would enable you to correctly diagnose male hormone deficiency? A. No.

Q. Would the symptoms which I have just described to you and to which you have given replies indicate necessarily male hormone deficiency?

A. You mean the nervousness and all those symptoms?

Q. That is correct. A. No.

Q. Without attempting to give a percentage, Doctor, do you have an opinion as to whether the incidence of male hormone deficiency is a common or rare phenomena? [177]

A. Rare, very rare, I would say.

The Court: Even in old men?

A. Yes, your Honor.

The Court: Impotency has nothing to do with it?

A. Nothing whatsoever; nothing whatsoever.

Mr. Danielson: Could the doctor explain that point, your Honor?

The Court: Yes. I would like to have him do so.

The Witness: I beg your pardon?

Q. (By Mr. Danielson): The fact that impotence is not a symptom of male hormone deficiency.

A. Well, impotence may be due to a variety of

(Testimony of Norris J. Heckel, M.D.)

diseases and causes, for instance, syphilis can produce it. One of the most common causes of impotence is of psycho-genic origin.

Q. And by that you mean what, Doctor?

A. Worry, fatigue, mental strain. Many people are not—a good many men I would say imagine that they are impotent. Their impotence is brought on by imagining that they are impotent.

The Court: It comes with age, at some period, does it not?

A. It is a natural process. Various stages of impotence occur with the natural process of aging, I mean the sex organs go through the same stages as other parts of the body. [178]

Q. (By the Court): Well, does sterility have anything to do with it?

A. No. Obviously, an impotent man is sterile, I mean because of his impotence he cannot discharge the spermatozoa, but a sterile man is not necessarily impotent.

Q. (By the Court): I was thinking of sterility in connection with the need for a greater supply of the hormone.

A. I did not understand your Honor.

The Court: I was thinking of sterility in connection with the need of hormones of the male type. There is no connection there?

A. No, no, no. Not unless, again, the sterility is due to an atrophy of the testes caused by a deficiency of the hormone——

The Court: Yes.

(Testimony of Norris J. Heckel, M.D.)

The Witness: —then, that would be the result.

Q. (By Mr. Danielson): But that, again, would be one of those extremely rare conditions, is that correct, Doctor?

A. Yes, I would say it would be pretty rare.

Q. Now, Doctor, in your practice as a urologist, have you had occasion to determine, aside from these symptoms we have just mentioned, any of the results of hormone therapy? A. Yes.

Q. What are some of your observations about that?

A. You mean in treatment of prostatic cancer, for instance? [179]

Q. Yes.

A. Well, from the use of methyl testosterone we know, now, that the use of that material will aggravate prostatic cancer.

We know, now, that the use of stilbesterol, the female sex hormone, will produce a retrogression of prostatic cancer.

We know that the use of male sex hormone in any form will do wonderful things to these individuals that are suffering from a deficiency of this hormone.

Does that answer your question?

Mr. Danielson: Yes, I believe it does, Doctor.

Q. Now, Doctor, directing your attention to the use of methyl testosterone tablets containing 25 milligrams each of methyl testosterone, do you have an opinion as to whether a dosage of one tablet a day, for indefinite duration, would produce any of the effects which you have just described?

(Testimony of Norris J. Heckel, M.D.)

A. Yes, it would.

Q. What effect could that have on a prostate cancer?

A. It would cause it to grow and disseminate.

Q. In the event, Doctor, you had a patient with an early or incipient prostatic carcinoma, in your opinion would the use of methyl testosterone be indicated?

A. Oh, definitely not, contra-indicated.

The Court: Will you read the question and the answer? [180]

(Record read by reporter.)

Q. (By the Court): Would the use of the drug be indicated?

Mr. Danielson: Would it be recommended?

The Court: Oh, yes.

A. That is the same question; the same answer.

The Court: Yes.

Q. (By Mr. Danielson): Doctor, it would follow, then, that the use of the same drug, one to two tablets daily for an indefinite duration—you would have the same answer, I presume?

A. It would be worse.

Q. Are you familiar with linguets of methyl testosterone containing 5 milligrams each?

A. Yes.

Q. Do you have an opinion as to whether a dosage of two tablets three times daily of 5 milligrams each, continued for an indefinite duration, would have an effect on these conditions?

(Testimony of Norris J. Heckel, M.D.)

A. The same effect, but it would not be produced as rapidly.

Q. Do you have an opinion, Doctor, as to a dosage of tablets containing 5 milligrams—linguets containing 5 milligrams of methyl testosterone each, with a dosage of three to four linguets per day, as to whether they would have such an effect?

A. The same thing. [181]

Q. Now, Doctor, as a urologist, you have occasion to conduct examinations to detect prostatic cancers, is that not correct?

A. That is right.

Q. Would you explain the effectiveness of a palpation or rectal examination in diagnosing prostatic cancer?

A. Prostatic cancer?

Q. Yes.

A. Well, in the majority of men, the diagnosis in the majority of instances is by rectal examination.

Q. Can it be detected in early stages?

A. Yes. But, in early stages, early prostatic cancer, it may be necessary to supplement the rectal examination with a biopsy. In other words, there are two other conditions that may simulate an early prostatic cancer.

Q. Will you explain that?

A. One is a stone in the prostate and the other is an area of inflammation and those are the only two things that I know of that would simulate the prostatic cancer. Most prostatic cancers, the majority of prostatic cancers arise in the posterior lobe of the prostate, which can be felt very easily on rectal examination. [182]

(Testimony of Norris J. Heckel, M.D.)

Q. Doctor, what procedure is necessary to distinguish these other two conditions from prostatic cancer?

A. Examination of the prostatic fluid for the presence of an infection, an X-ray picture of the prostate gland, of the area of the prostate gland.

Q. Do those examinations require special training, Doctor? A. Yes; I would say so.

Q. Can a diagnosis of prostatic cancer be accurately made by subjective symptoms?

A. No.

Mr. Danielson: No further questions. [183]

* * *

Cross-Examination

By Mr. Elson:

Q. Doctor, you stated this morning that the incidence of male hormone deficiency, in your opinion, was very small? A. That is right.

Q. When you had that in mind or when you made that statement, did you have in mind—I will withdraw that. Just prior to your making that statement, you were speaking of eunuchoidism?

A. That is right.

Q. And that, of course, is only one manifestation of a male hormone deficiency?

A. That is right.

Q. What are the other manifestations of it? I mean without anything that pertains to surgery or a laboratory test.

(Testimony of Norris J. Heckel, M.D.)

A. You say symptoms of male sex hormone deficiency?

Q. Not quite that. I mean the symptoms which Mr. Danielson read to you this morning, which pretty nearly cover [185] all of the field, don't they?

A. Yes; I think that is true.

Q. What I have in mind is this. I mean a man who has knowledge like a general practitioner. This man is not a specialist such as you and these other gentlemen who have testified. His knowledge lies in the field of general practice, such as lawyers experience in the field of general practice. And the man complains of several of the symptoms that were read to you this morning. In your opinion, what would that general practitioner, as a practical matter, do to assist that man in being relieved?

A. The first thing he should do is to make a careful examination of the patient to see if he can find out what is producing the symptoms. As I said this morning, there may be a number of diseases that will produce these symptoms. Do I make myself clear?

Q. Yes. I presume that one of those things, first things, that he would do would be to take a history of the patient.

A. That is right.

Q. And, as a matter of fact, that is what the average doctor does to any patient that is new?

A. Yes.

Q. Then, if the history of the patient didn't disclose any condition dissociated with, putting it broadly, male hormone deficiency, what, in your opinion, would the doctor [186] do?

(Testimony of Norris J. Heckel, M.D.)

A. Examine the patient, the next procedure would be, a physical examination.

Q. A physical examination? A. Yes.

Q. That would include the usual examination that we are all familiar with, would it?

A. Yes; from head to foot.

Q. Tell me this. The average practitioner, the general practitioner, as briefly as you can, would make what sort of an examination?

A. That is a very good question and a very important question. He would go over the patient, examine his heart, lungs, reflexes and pupils and neck, chest; and then, suppose we will say for the sake of the argument that, after he had done that, he couldn't arrive or he did not have an opinion on what might be wrong with this patient; then the next thing that he would do, in all probability, would be to examine the urine to see whether there was any sugar in the urine, which would give him a clue that this patient might have diabetes, which would produce this sort of symptoms. We will assume there was no sugar, and then he would look at the urine to see whether there was albumin in the urine or casts in the urine, which would indicate that the patient, in all probability, would be suffering from Bright's Disease or some kidney disturbance. Let's assume for the sake of the argument [187] that was normal; then he would take the patient's blood pressure and see whether it was normal. Maybe the patient had a hypertension. Then, let's assume for the sake of the argument that his blood pressure

(Testimony of Norris J. Heckel, M.D.)

was normal and his urine was negative; he would probably take a blood count, as the next procedure, to see whether the patient was suffering say from anemia or had some blood disturbance.

Q. May I stop you right there? A. Yes.

Q. To be clear on it, first, all of these things cannot happen in one day, can they?

A. Oh, yes.

Q. I mean he would take a urine specimen and a blood sample and all like that but he wouldn't get the results on it until he has sent it out to a laboratory?

A. He might send it out but he could do it himself. If he would send it out, he probably wouldn't have that evidence until the next day.

Q. What I was thinking of was the ordinary general practitioner that a person goes to, whether he was equipped to conduct those tests or not himself or whether he had to send them out, and then say a day or two later the man came back.

A. Yes.

Q. You may go ahead. [188]

A. Where was I?

Q. Maybe the reporter can help you out.

A. Well, I can remember it. We got as far as the blood pressure. With the blood pressure say normal and that didn't explain the symptoms that the patient complained of, then you would get into the various should I say more complicated laboratory procedures. There might be some indication that the patient had a gastro-intestinal disturbance

(Testimony of Norris J. Heckel, M.D.)

and an X-ray picture of the stomach or an X-ray picture of the colon should be taken or a basal metabolic test made to discover whether or not he had some disturbance of his thyroid, for instance.

Does that answer your question?

Q. Yes. And I suppose there would be included in that a rectal examination?

A. Oh, yes; in the physical examination.

Q. And, if he found nothing on palpating the prostate that appeared suspicious, would it be reasonable to assume that the man was probably suffering from a male hormone deficiency?

A. No; I can't agree with that.

Q. I realize this, that you are a urologist; you are in a very specialized field. And we are talking now about the general practitioner who is not a specialist in anything. He is a master of all and so on. He is the type of doctor who is most predominant, isn't he? [189]

A. That is right.

Q. We are safe in assuming, aren't we, that that type of a doctor is not going to be blessed with the specialty that you, Dr. Macdonald, Dr. Thienes and some of these other gentlemen have?

A. That is right.

Q. Now, just looking through and getting down to earth on this thing, is it a fact that such a doctor, who had gone through a complete physical examination of that patient and had been unable to find anything that looked suspicious, because of any of these symptoms, as a matter of actual practical fact

(Testimony of Norris J. Heckel, M.D.)

—wouldn't such a doctor suggest testosterone to the man to be tried for a period of say four to six weeks and see if those symptoms were relieved, as a common sense matter?

A. He might but he shouldn't.

Q. We are not talking about that. We can get into fine distinctions in medicine, and in law for that matter, as to what a man should do but they don't. We can talk in the same way about lawyers preparing cases. They should but many times they don't. Now, let's forget about what they should do and draw on your knowledge as to what the average man in general practice would do. As a matter of fact, wouldn't he do about just as I have stated?

A. I really doubt it; I really do. I doubt [190] that.

Q. Doctor, you stated something this morning that really puzzled me, among many other things, that there were very few men who went through the climacteric period.

A. That is right.

Q. How can you explain, if you can, then, the vast quantity of testosterone that is sold by the Schering Corporation, the Ciba Pharmaceutical Company, and Roche-Organon?

A. Well, in answer to that question, the only thing I can say is this, that I don't know of anyone, any doctor, any scientist, any investigator, that has presented evidence by which one can make a definite diagnosis of the so-called male menopause or the male climacteric. I, myself, in my experience, have never been able to make such a diagnosis as a male climacteric.

(Testimony of Norris J. Heckel, M.D.)

Q. Right at that point, isn't it a fact that very frequently in the case of you specialists your diagnosis may not be a hundred per cent correct?

A. Absolutely.

Q. And wouldn't the margin of error increase greater, in your opinion, with the general practitioner?

A. Increase greater?

Q. Yes.

A. Do you mean in making a diagnosis?

Q. In making a diagnosis, wouldn't the margin of error be greater with the general practitioner than with you gentlemen [191] who are specialists?

A. I think that is true; that is right.

Q. So, therefore, it could be very probable in the case of a general practitioner that a man might be going through the male climacteric and he wouldn't diagnose it correctly?

A. Well, what is the male climacteric? I don't know.

Q. Well, frankly, I have seen it spoken of in the literature and you probably have, too, as a condition of something or other that is comparable but not the same as the female menopause. [192]

A. As I have described the symptoms and the differences in the male climacteric?

Q. No. But it is a change of life, if you want to call it that?

A. I don't know what it is. I have never read or in talking with my colleagues learned what it was. As far as my knowledge goes, I have never been able to find an article written by anyone in which

(Testimony of Norris J. Heckel, M.D.)

they can tell how to make such a diagnosis as the male climacteric.

Q. It is referred to frequently in the articles as the male climacteric, is it not?

A. Oh, very frequently in layman's magazines and medical publications.

Q. I am going to move now over into something else before I forget it. Do you know of a doctor by the name of Deming?

A. Yes, sir; Clyde Deming of Yale University. I know him very well.

Q. Well, it is Albert Hemming.

A. I can't recall him right at the moment.

Q. To refresh your mind, I am told that he was formerly on the research staff of Ciba Pharmaceutical Corporation.

A. I can't recall him right at the moment.

Q. Incidentally, isn't it true that the body does not store hormones? [193]

A. Within a reasonable length of time, that is true. I mean most of the hormones. And I am speaking only of the male now.

Q. That is all I am talking about.

A. It is excreted in a period of 24 hours, I think, roughly, although I can't vouch for that statement.

Q. That would be sufficient, wouldn't it, for us to say with accuracy that the body does not store hormones? A. Yes.

Q. In other words, in 24 hours it is out of the body like in the food that we take?

A. Yes; I think that is true.

(Testimony of Norris J. Heckel, M.D.)

Q. You are aware, are you, that methyl testosterone may be sold, so far as any statutory requirements are concerned, without prescription?

A. I wasn't aware of it until just recently.

Q. Are you aware of the fact that at least in California it is not classed as a dangerous drug by the Department of Pharmacy?

A. I found that out this morning.

Q. I was talking about alpha estradiol this morning.

A. No; I didn't know that.

Q. Coming back to the amount that is sold by these three corporations that manufacture it, Schering, and Roche-Organon and Ciba, if you can divorce from your mind your own [194] experience as a urologist, wouldn't it appear to you that, in view of the hundreds of thousands of packages that are sold in the aggregate by all three per year, that the product was indicative of considerable benefit to many, many, many men?

A. No question about that at all; wonderful. But there are many things with this hormone, that was claimed for it, that is now proven that it was of no benefit. For instance, it was supposed to have been a cure for prostatic enlargement. It was supposed at one time to have been valuable in the treatment of sterility. And those conditions now have been proven to have been false. There is no argument that this hormone produces dramatic results. There is no question about it, if it is used properly, that is, when you think that you can take a female male and make that individual into a man and establish him back

(Testimony of Norris J. Heckel, M.D.)

into his community and make him a perfectly normal male, it is really amazing and astounding. [195]

Q. (By Mr. Elson): And isn't it equally astounding that a person who is suffering from a male hormone deficiency manifesting the symptoms that Mr. Danielson read to you this morning, would find that those symptoms or the majority of them would disappear?

A. Certainly, if he has a testicular deficiency.

Q. I am predicating it all on that.

The Witness: That is right.

Mr. Elson: Because that I don't question.

The Witness: Absolutely wonderful.

Mr. Elson: I don't question it. I might say that if I thought for a moment that that literature there represented that this product would be good for those conditions, even though they did not arise from a hormone deficiency, I would not be in this courtroom.

Q. In other words, the methyl testosterone, testosterone propionate has proved an immeasurable benefit?

A. There is no question about it.

Q. To thousands and thousands of men?

A. Well, I don't know—I would say that they could even go into the thousands over the world, yes, I think that would be true.

Q. We could say hundreds of thousands probably and be pretty safe?

A. I question that. That seems to be—maybe. I [196] don't know.

(Testimony of Norris J. Heckel, M.D.)

Q. Now, on this cancer business, you stated this morning, that is, I understood you to say that as a fact methyl testosterone would accelerate the growth of an incipient cancer of the prostate.

A. That is right.

Q. Do you know of any clinical evidence where that has been demonstrated as a fact?

A. Yes, sir.

Q. Where?

A. My own patients that I have observed.

Q. Was it an incipient carcinoma?

The Witness: Can I explain it?

Mr. Elson: Yes.

The Witness: Would you like to have it?

Mr. Elson: Yes.

A. A patient that was previously operated for a prostatic enlargement, prostatic hyperplasia or benign prostatic enlargement, the same thing, and for some reason or other, the histological sections revealed that this enlargement was benign or not cancerous, and rectal examination also confirmed the histological reports and studies. This patient for one reason or other was given methyl testosterone in a period of four or five weeks, five weeks I think, it doesn't make much difference, and that individual developed a prostatic cancer [197] while he was under—not developed, that is not quite the word I want to say—at least he did develop a prostatic cancer.

Q. (By Mr. Elson): Well, medically and scien-

(Testimony of Norris J. Heckel, M.D.)

tifically, does that prove that that cancer was caused by testosterone?

A. No. We don't know the cause of cancer.

Q. Medically and scientifically, does that prove that the growth of the cancer was accelerated by testosterone or something else?

A. I think it does, for the simple reason that it is not—that the growth of this cancer was so spectacular, was so rapid, that it did not follow the usual pattern of an ordinary patient that has a prostatic cancer, in other words, the individual that has prostatic cancer, we will say an incipient prostatic cancer, it may go on for four to five months before it produces any symptoms whatsoever. And here, under the stimulation, if you please, of methyl testosterone over a period of four or five weeks, the changes in this prostate and even outside of the prostate were extensive.

Q. Well, isn't that a presumption on your part, that that was the result of taking testosterone? In other words, what I mean is this: that you have no proof that that was the cause of it, rather than something else?

A. Well, I don't think that cause—I mean that I don't think that testosterone in any form causes prostatic cancer. [198] I mean we don't know what causes it, because it has been definitely proven that testosterone in any form will activate and spread prostatic cancer.

Q. (By the Court): What do you mean by spread, Doctor? Just pardon me.

(Testimony of Norris J. Heckel, M.D.)

A. Metastasize to other parts of the body. It goes into the lung and into the bones.

Q. (By Mr. Elson): Who has proven it, leaving apart your case?

A. I could give several others.

Q. Have you found any in the reported literature, any of it in the literature?

A. I think Dr. Huggins has reported that. I can't tell you right off at the moment the journal that it was published in.

Q. Recently?

A. If my memory does not fail me, I would say in the last two years.

Q. Well, then, prior to the last two years, say from 1947 and prior thereto, was there anyone who reported as a definite fact that a cancer of the prostate had been accelerated in growth by testosterone?

A. Well, of course, this whole prostatic cancer problem and its relationship to hormones is a relatively new thing. I think it was only in 1940 that Dr. Huggins came out [199] with this monumental work of his, that definitely showed and proved that you could cause a regression of prostatic cancer by the administration of estrogens, for instance. This whole thing is a relatively new thing.

Q. Well, then, prior to 1947, isn't it a fact that whether or not testosterone would accelerate the growth of a cancer in the prostate was a matter of conjecture?

(Testimony of Norris J. Heckel, M.D.)

A. Well, based on clinical evidence, it was thought that——

Q. That is what I mean. A. Yes.

* * *

Q. (By Mr. Elson): Are you familiar with the work of Dr. Nathanson that I spoke of this morning?

A. No, I am not too familiar with it. I think most of his work is in the field of gynecology, isn't it? I know who he is.

Q. I think you are right. I think you are right, but in this—this was a symposium that I referred to this morning in my examination of Dr. Macdonald. It was Recent Progress in Hormone Research, Volume 1, Proceedings of the Laurentian Hormone Conference 1947. [200]

Now, Dr. Nathanson in that article, and the article is entitled "Endocrine Aspects of Human Cancer," he discusses carcinoma of the breast and so on and also cancer of the prostate gland. Now, generally speaking, and I will try to state it in substance (I think I am correct), I shall read that portion of his article. He speaks of castration or that following castration in some cases there has been evidence of the recession or inclination to dormancy of a prostatic cancer. A. That is right.

Q. And he speaks of the implication by some—that as a result of that testosterone, accelerates the growth of a prostatic cancer, because after castration of course testosterone is not produced by the testicles. A. That is right.

(Testimony of Norris J. Heckel, M.D.)

Q. And so, that is the conclusion—or he does not state it as his conclusion; it is an implication or presumption. However, he poses this question and I wonder if you agree with it: that following castration there is a pathological change in the body, the pituitary gland is stimulated, action of the pituitary is stimulated, action of the adrenal glands are stimulated, and whether or not it might be because of that excess stimulation that the growth of the prostatic cancer is inhibited? Do you think there is any merit to that idea? [201]

The Witness: I am sorry. I did not quite follow that language, the last sentence of yours. Right up until the last sentence I did not quite follow that.

Q. (By Mr. Elson): Well, now, let me start over again: That after castration there is a pathological change in the body which takes place?

A. Yes.

Q. That the pituitary glands or pituitary gland and adrenals are closely connected in their activity——

A. That is right.

Q. ——with the testes. A. That is right.

Q. That, when the testes are removed, the pituitary is stimulated to secretions greater than that which they would prior to castration; the same is true of the adrenals?

The Witness: Did he say that?

Mr. Elson: That is what I understood him to say. “Orchiectomy,” which is castration——

A. That is right.

Q. ——“although removing one source of andro-

(Testimony of Norris J. Heckel, M.D.)

gens may permit increased pituitary activity, thus stimulating organs such as the adrenal gland to increased androgen production.”

A. That is right.

Q. That is what I mean. All right. Now then, can you say as a fact, Doctor, that the increase in secretion by the [202] pituitary and the increase in production by the adrenals or some other pathological changes that has taken place in a man's body following castration is not as a fact responsible for inhibition of the growth of a prostatic cancer?

A. No. It would not inhibit the growth. It would stimulate—it might stimulate the prostatic cancer. It might stimulate it.

Q. What would?

A. I follow your thought very well. As a matter of fact, you expressed it fine. I mean, what you do when you castrate the individual, you release the governor from the pituitary and the pituitary throws out, increases its gonadotropic activity. By increasing its gonadotropic activity it stimulates the adrenal, and it is now well established that the adrenal also produces androgens, and the presence of the increased androgens in the body, as a result of the stimulation of the adrenal by the pituitary might activate or cause to grow the prostatic cancer that is there, and that is why we have, apparently why, or that is a theory at least why some of these patients are not relieved or their prostatic cancers do not regress. That is a result of the castration.

Q. But it is still a theory, isn't it?

(Testimony of Norris J. Heckel, M.D.)

A. That is right—well, they have found that the adrenals do produce androgens. That is not a theory.

Q. No. I understand that. [203]

The Witness: And it is not also a theory—this has been done on experimental animals, where they have castrated, for instance, the rat; they hook two rats together. Then they castrate one rat and that increases the gonadotropic activity of the anterior lobe of that particular rat and as a result of that, they produce changes in the other rat that is hooked up.

Q. (By Mr. Elson): I know, but right at that point, it doesn't follow necessarily that experimentation with animals is going to produce the same results as with humans? A. That is right.

Q. And it still is simply theory that castration stimulates the activity of the pituitary which in turn stimulates the production in the adrenals and so on, and that the growth of the cancer is increased?

A. I would say 95 per cent of that statement has been proven.

Q. What was the theory that you were talking about, then?

A. I don't know. What theory?

Mr. Elson: Read back to him. You mentioned something that was still theory and I just want to be certain. Can you go back there, Mr. Reporter?

Mr. Danielson: I believe he said this was the theory in the sense of rational— [204]

(Record read by the reporter as follows:

("And the presence of the increased andro-

gens in the body as a result of the stimulation of the adrenal by the pituitary might activate or cause to grow the prostatic cancer that is there, and that is why we have, apparently why, or that is a theory at least why some of these things are not relieved, or their prostatic cancers do not regress. That is a result of the castration.”)

The Witness: That last part is theory, but the rest——

Mr. Elson: Yes, that is right.

The Witness: Yes.

Mr. Elson: I think we understand each other.

Q. The fact still remains, though, doesn't it, that men are castrated, I suppose every day, for the purpose of inhibiting the growth of a prostatic cancer?

A. That is right, except there are not as many men being castrated today as there were five years ago.

Q. Well, that may be true.

A. Yes, that is true.

Q. You know more about that than I do.

A. Yes.

Q. I shouldn't say “may be.”

The Witness: Yes.

Q. (By Mr. Elson): Are you familiar with this book, *Endocrinology* [205] of *Neoplastic Diseases*, a symposium? A. Yes, sir.

The Court: Well, you raise a situation there that seems queer to me.

Q. You say that castration does or at least by

(Testimony of Norris J. Heckel, M.D.)

theory it did retard cancerous growth in the prostate? A. Yes, that is right.

Q. Well, it merely retards? It would not heal of its own accord, would it?

A. It is never—your Honor, although Dr. Huggins has some five-year cures, so-called five-year cures as a result from castrating men that had prostatic cancer, no one so far as I know has ever made the claim that castration or any of these various forms of therapy that are now used will definitely cure the disease. Now, they will make them clinically well so they can again resume their work.

Q. (By the Court): Well, eventually, in practically all cases, in fact it is done every day, isn't it, removal of the prostate gland will get rid of the cancer?

A. Well, that is in early prostatic cancer. That is where the cancer is confined to the gland itself. It has not been spread. When they take out the whole gland, they can get rid of the cancer.

Q. (By the Court): Well, the spread is no longer—

A. No. After it is spread, and then unfortunately [206] about 95 per cent of the men, by the time they come to their physician for their relief of the symptom, they already have a prostatic cancer that is spreading beyond the confines of the gland itself.

Q. (By the Court): Castration would not affect that in any way?

A. Yes. Now, in those instances, that is when

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the castration is indicated, after the cancer has extended beyond the limits of the gland itself and where an operation cannot be done. Now, with an early prostatic cancer, then you would not castrate the individual, if you could take all the cancer out by removing the gland.

Q. (By the Court): Supposing that it extended to the kidneys?

A. It doesn't make any difference so far as castrating an individual is concerned, kidneys, chest——

Mr. Neukom: Will you show the court one of the slides of the prostate here? This is one of the slides we showed yesterday.

The Witness: You see, when the cancer is confined right here (indicating), when it is localized, right here, when you go in and you take this whole gland out, then you get rid of the cancer, just like you take off a breast in a woman.

The Court: Yes.

The Witness: But prostatic cancers unfortunately metastasize [207] quite early, it goes to other parts of the body. Suppose it goes to the chest.

Q. (By the Court): It is more likely to do it than cancer originating in other parts?

A. Yes, than in the bladder, for instance, that is right. Then, with that individual where it has gone to other parts of the body, extended to other parts of the body, then, obviously it would not do any good to take this out, or where you have cancer in other

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parts of the body. In those two instances, there are two forms of recognized therapy, now. One is to castrate the individual or give him estrogens or female sex hormones.

Q. (By the Court): Well, castrating, would that do any more good than to stop the spreading?

A. Well, it will produce—it will cause a regression or a shrinking up of these metastatic lesions.

The Court: Well, that is all very new to me.

The Witness: Yes, it is. This thing has just developed in quite an amazing sense. For instance, I can show you X-ray pictures of a man's chest that has just been riddled by these metastatic lesions, and then put him on estrogenic therapy, this diethylstilbestrol that they are talking about here, and in six months time take an X-ray picture of his chest and you cannot see these metastatic lesions, they have shriveled up, they have disappeared—really an amazing [208] thing.

Mr. Elson: Let that go in as government's Exhibit 16, and that is the photograph or a duplicate—it is a photograph which is a duplicate of one of the pictures which was on the slide and explained yesterday by Dr. Nelson.

Mr. Danielson: Then, No. 16 is the photograph to which the witness was referring in making his last explanation.

The Clerk: That is Government's Exhibit 16 in evidence.

(The photograph referred to was marked

(Testimony of Norris J. Heckel, M.D.)

Government's Exhibit No. 16 and received in evidence.)

Q. (By Mr. Elson): Doctor, you spoke about this being just recent. How recent is this?

A. Well, to be exact, I think 1940.

Q. 1940, when Dr. Huggins——

A. ——first came out with his experimental evidence.

Q. Then, when did it become the consensus of medical opinion that castration to inhibit the growth of a prostatic cancer was not so necessary as had been thought to be before?

A. Well, that still is a debatable question. The only way I could answer that is to tell you what is going on in the larger clinics.

Q. I don't think we need that. I mean as I get it, it is still a debatable question?

A. Of whether they should be castrated or have estrogens, or both. [209]

Q. Now on this incipient business, incipient means beginning, does it not? A. Early.

Q. Well, Taber's Medical Dictionary defines it as beginning. A. Yes.

Q. Would you agree with that definition?

A. Yes, I will agree with that.

Q. Now, when a cancer of the prostate is beginning, wouldn't it be almost impossible in the vast majority of cases to even know that it was there, say by—I am not talking about you as a urologist—I am talking about our general practitioner?

A. If a general practitioner is familiar with

(Testimony of Norris J. Heckel, M.D.)

rectal examinations, an early prostatic cancer could or should be suspected. Now, we have to define what we mean by early incipient. Now, if it is the size of a pin head, then I question whether any one could do it.

Q. But, after all, they start from one cell, don't they?
A. That is right.

Q. And they start from one cell and they grow wild and multiply, that is what generally speaking in layman's language what a cancer is, isn't it?

A. Yes, I would say that. [210]

Q. A wild uncontrolled cell?

A. Yes, that is right, exactly what it is.

Q. So, in its incipency or beginning, or if we want to get technical about it, it is the first cell, isn't it?
A. That is right.

Q. But, to be reasonable——
A. Yes.

Q. ——wouldn't it be fair to say that a prostatic cancer in its incipency was one that was beginning and whether or not it was discoverable depended upon how far it had grown?

A. Yes, you should—you can discover it when it is about the size (I am just using some yardstick), about the size of a split pea, we will say, or something like that.

The Court: Now, pardon me. This is by-passing now. Now, what I would like to find out there: There are many tests to determine whether a cancer exists in a human body, aren't there?

A. No, your Honor. You mean laboratory tests

(Testimony of Norris J. Heckel, M.D.)

or blood tests? There are no blood tests right at the moment that are——

Q. (By the Court): There are urinary tests?

A. No, no, no.

Q. (By the Court): There is a doctor here in Los Angeles, in Glendale, a Dr. Carpenter, hasn't he got a urinary test?

A. No, not to discover cancer that I know of. Now, [211] there is a Dr. Papanicalou from New York, who came out several years ago with the strain and, for instance, you would massage the prostate, we will say, massage the prostate, get the prostate fluid collected on a slide and then he would stain that slide with some special stain, and he is a very extraordinary man in cell physiology. I mean he made a special study of that, and he can tell by the examination of that slide whether there are cancer cells from the prostate. That was true. But, by that time you can also make a diagnosis by a rectal examination.

Now, Dr. Huggins. There was a good deal of publication in the newspapers just recently and he reported these investigations at Detroit about three weeks ago I think. He is working on a test that he has developed by examining the blood and this was about discovering the presence of cancer in the body, but I understand that that is not a specific test, that other diseases will also give a positive test, like tuberculosis, for instance, as I understand.

The Court: Pardon me for interrupting you there, but I rather wanted to get that in my own

(Testimony of Norris J. Heckel, M.D.)

mind, as to whether there was any different methods by which cancer could be determined before it just became——

The Witness: Clinically evident?

The Court: Yes. A. No, no. [212]

Q. Doctor, we want to keep in mind this, coming back again to the charges in the information, that it may be dangerous, that is, methyl testosterone, because it may accelerate sterility and the growth of a prostatic cancer. A. That is right.

Q. And that is that would be a case where a person could, as the law permits him to do, go and buy methyl testosterone at a counter, without a prescription. That is what we have to keep in mind. We have also got to keep in mind the average circumstances as we talk about our reasonable man. And I think it is fair to say that we must keep in mind the average person who would go to the average competent general practitioner in a community and whether or not, if he went to such a doctor, before he bought any testosterone, and he had an incipient carcinoma of the prostate,—whether such a doctor, not you, would be able to find any incipient carcinoma of the prostate in that man. Now, if he did, I take it from the literature that, out of at least an abundance of caution, he would caution him against using methyl testosterone. But let's take that same individual who a few days or a week later complains of these symptoms and the doctor decides

(Testimony of Norris J. Heckel, M.D.)

that he is going to try him on methyl testosterone to relieve him of those symptoms. We are talking about an incipient carcinoma That he doesn't find anything that makes him suspicious as such a doctor would go about it. There wouldn't be [213] anything so far as cancer of the prostate is concerned to prevent him from prescribing testosterone, would there?

A. If there is a definite indication for prescribing it.

Q. We are talking about an indication of how—or we will assume in our question that there was an indication to him of a male hormone deficiency and that the doctor had examined the man as such a doctor would do and had concluded that there was no suspicion of carcinoma of the prostate. I take it that such a doctor wouldn't hesitate to try the man on testosterone to see if he was relieved of his symptoms, is that right?

A. Oh, I question that.

Q. Just try and divorce this business from you.

A. Yes; I know.

Q. Have you ever been in general practice?

A. Yes, sir.

Q. I don't know how long ago it was but let's try and project yourself into the shoes of a general practitioner. Don't you think it is reasonable after that that the doctor is going to prescribe methyl testosterone for him?

A. I am sorry; I can't agree. I don't think the general practitioner would. Most general practitioners are very good doctors. The chances are 99

(Testimony of Norris J. Heckel, M.D.)

times out of a hundred the general practitioner would find some specific reason for this [214] man's symptoms.

Q. You are putting something into my question now—— A. I am sorry.

Q. ——that isn't there.

A. All right; I am sorry

Q. Would he be safe—I will withdraw that.

Don't you think that that doctor would ordinarily, under the circumstances, try the man on methyl testosterone? A. I don't think he would.

Q. You don't think he would?

A. No; I really don't. I don't think he would.

Q. Let's assume that he did. A. All right.

Q Or let's assume before we get there that the doctor found nothing that was suspicious of cancer and so told the man. It necessarily follows, if such a warning had been on the package, it wouldn't have meant anything to the individual, would it, because the doctor had told him that he found nothing in the way of cancer of the prostate?

The Court: Due to the rather peculiar question there to the witness—isn't it true with relation to general practitioners, young and old, that they are influenced psychologically by different experiences and discoveries and what they have read and the impression that was made on them with respect to the patients? [215]

The Witness: I think that is true.

The Court: Don't some of them lean very much in favor of certain specifics and others, for some

(Testimony of Norris J. Heckel, M.D.)

reason or other, form somewhat of a prejudice against them, maybe from some experience that they had?

The Witness: That might be true; yes.

The Court: At the present time, or a few years back, a very large percentage of the ordinary practicing physicians were giving lots of consideration to sulphonide drugs?

The Witness: Yes.

The Court: But it has been restricted considerably in the last few years and apparently the majority of them now go in for penicillin for just about anything?

The Witness: It all depends. They now know that these antibiotics, the sulpha drugs and penicillin, and now we have a new one, have a specificity for certain organisms, for certain bacteria, and an organism that the sulpha drugs would not influence, penicillin would. They now know a little bit more about that than several years ago.

The Court: The only reason I asked about that was on account of a question that counsel asked you, as to what the average practitioner would be likely to do with reference to this testosterone.

The Witness: Yes.

The Court: And I had a query in my mind as to what the [216] average doctor would know or think about testosterone; that some of them might be enthused about it and others might be prejudiced. Do you think so?

The Witness: That is true; that would be true, I think.

(Testimony of Norris J. Heckel, M.D.)

Q. (By Mr Elson): Doctor, one of the questions that the court propounded to you made me think of something here. Coming back to our average practitioner, the average competent practitioner, general practitioner, he is a pretty busy man even today, isn't he? A. Yes; I would say so.

Q. And is it also true that with that average individual he simply does not have enough hours in the day to do his work and do all of the studying and reading of literature that he would like to do?

A. That may have been true during the war but I think now that that situation is not as prevalent.

Q. Then he couldn't take care of all his patients, that is, during the war? A. That is right.

Q. And there are many articles that have appeared, just as with we lawyers, that he ought to read probably but doesn't? A. Yes

Q. So isn't it a fact that a great deal of the working day-by-day information that that general practitioner receives [217] as to the efficacy or contra-indications and so on of a particular drug is furnished to him by the detail man from the large manufacturer suppliers, together with the literature supplied to that detail man by the manufacturer?

A. With the various county medical societies, state medical societies and post-graduate studies that they have, I would say, in answer to your question, that that is not as prevalent as one might think. It is true that large pharmaceutical concerns do send out lots of literature.

Q. And it is good information, isn't it?

(Testimony of Norris J. Heckel, M.D.)

A. And a lot of it is very good information.

Q. For instance, you take outfits like Ciba, Schering and Roche-Organon, and they maintain, do they not, large and various research staffs?

A. That is right.

Q. Isn't it a fact that the information that they supply in the literature to the doctors is right abreast with the times?

A. In general, yes, although——

Q. Although you disagree with some of it?

A. Some of it; that is right.

Q. However, as a practical matter, the average general practitioner is going to rely on what he reads in literature from such organizations, isn't he?

A. Not always; no. [218]

Q. In the vast majority of cases?

A. Well, of course, that is a variable thing. I don't know how you can answer that.

Q. Haven't you heard this time and again, that some doctor kicks about some product and he said, "That is not what the detail man told me it would do"? A. I have heard that statement.

Mr. Elson: I don't think I have any further questions.

The Court: One will have nothing but Squibb's and another nothing but some other drug.

Mr. Elson: I have no further questions, Doctor.

Mr. Danielson: I have a few questions to clear up a few points.

(Testimony of Norris J. Heckel, M.D.)

Redirect Examination

Q. (By Mr. Danielson): Doctor, in the first place, among medical men is not cancer deemed to be early or incipient when it is small enough to be detected yet susceptible of treatment?

A. That is right.

Q. Doctor, assuming a doctor who is administering testosterone to a male human patient, does he not keep that patient under regular examination or periodic examination during the treatment?

A. Yes, sir.

Q. And for what purpose is that? [219]

A. To detect any deleterious results that might occur.

Q. And if any indication of a prostatic cancer is itself determined, what does he do?

A. He stops the treatment.

Q. Doctor, do you know whether or not there is any manner in which the general practitioner does receive a constant flow of advice from the specialists and clinics?

A. Oh, yes. I should say probably two or three times every month I go to the various county medical societies and State medical societies, where we have post-graduate studies, to discuss recent advances, concerning my specialty, for instance. That is, symposiums on urological subjects.

Q. Is that a general practice throughout the profession? A. Yes.

(Testimony of Norris J. Heckel, M.D.)

Q. As to the male climacteric, Doctor, will you define what you mean by male climacteric?

A. The word "climacteric" I would say means a change, some change, that occurs from what exists previously.

Q. In a female climacteric, which I believe is an accepted phenomena, —

A. That is right.

Q. —what are the findings or the principal characteristics? [220]

A. Those findings in the female climacteric are very definite. The woman ceases to ovulate. In other words, the ovaries cease to make ovum. And there are definite changes that occur in the ovaries.

Q. Does the production of the estrogens—

A. It changes; diminishes.

Q. Does that eventually stop?

A. I can't answer that question definitely. I am not an authority on women's troubles. I would say in some instances I think it does practically cease, and it has to be replaced by female sex hormones.

Q. If there were a male climacteric, what would be the findings of such a condition?

A. Well, if there were such a thing as a male menopause or male climacteric, there should be similar changes occur in the testes, that is, there should be a cessation of spermatogenesis. In other words, the testes would not produce spermatozoa, but spermatozoa is formed in the man, in the testes

(Testimony of Norris J. Heckel, M.D.)

of the man, as long as he lives. One of the highest spermatozoa counts I have ever observed was a billion which occurred in a man 70 years of age

Q. Would there be any comparable change in the production of the male hormone, testosterone?

A. Yes; there should. There should be a drop.

Mr. Danielson: No further questions. [221]

Recross-Examination

By Mr. Elson:

Q. There was something I wanted to ask you, Doctor, and I have forgotten it. I am not going to go into the subject of sterility except in this one particular, because I think that has been covered. You know of Dr. Hans Lisser and Dr. Robert Escamillo?

A. Yes, sir

Q. I am going to draw a shortcut. I don't think Mr. Danielson and Mr. Neukom will make me do it the hard way. In "The Urology and Cutaneous Review," Volume 46, page 87, 1944, they were reported to have said, in discussing the effect of testosterone upon the production of spermatozoa, and I am now reading, incidentally, not from the article but from a pamphlet put out by Ciba entitled "Androgenic Hypotherapy in Male Gonadism,"—the text of this says as follows, speaking of the effect of testosterone propionate and methyl testosterone on the testes: "On the other hand, there have been reported patients whose sperm counts increased after treatment to the extent that successful impregnation took place. Other authors have pointed

(Testimony of Norris J. Heckel, M.D.)

out that both number and viability of the spermatozoa can fluctuate during the continued use of androgens or that the count is 'of minor significance as compared to the enormous improvement obtained in all other respects'?"

Would you agree with that statement? [222]

A. Those patients were being treated for male sex hormone deficiency, were they?

Q. Surely.

A. Oh, certainly, I would agree.

Q. Doctor, in our discussion here I have assumed in any question in which the subject was relevant that we were speaking of a condition that resulted from a male hormone deficiency and nothing else.

A. Yes.

Mr. Elson: That is all.

Mr. Danielson: That is all.

ELMER BELT, M.D.

called as a witness by the government, being first duly sworn, testified as follows:

The Clerk: Your full name?

The Witness: Elmer Belt.

Direct Examination

By Mr. Danielson:

Q. What is your address, Dr. Belt?

A. 1893 Wilshire Boulevard in Los Angeles.

Q. Of what schools are you a graduate and what years and degrees, please?

(Testimony of Elmer Belt, M.D.)

A. University of California, Bachelor's, Master's and [223] Doctor's degrees; Bachelors in 1916, Master's in 1918, and Doctor's in 1920.

Q. That is M.D., Medical Doctor?

A. Yes.

Q. And what post-graduate training have you had, Doctor?

A. I did my urologic work with Dr. Frank Hinman at the University of California and then I went to Harvard's Teaching Hospital, the Dr. Bent Brigham Hospital in Boston, to work under Harvey Cushing in brain surgery.

Q. And you are a member of what medical or scientific societies, Doctor, if you will name a few?

A. The American Medical Association, of course; the American Urologic Association; the American Association of Railroad Surgeons; the International Surgical Association, and many others.

Q. Are you a Fellow of the American College of Surgeons, Doctor?

A. Yes, sir.

Q. And are you a Diplomate of the American Board of Urology?

A. Yes.

Q. Doctor, have you had occasion to prepare and publish any articles, medical and scientific literature?

A. Oh, yes. [224]

Q. About how many, would you estimate?

A. Thirty or forty, I suppose, but I have taken part in three books as co-author and published many articles.

Q. Have some of these articles or published books had to do with cancer of the prostate?

(Testimony of Elmer Belt, M.D.)

A. Yes. Most of them deal with the genito-urinary tract.

Q. Are you recognized in any biographical encyclopedia, such as Who's Who?

A. Oh, yes; I have appeared in Who's Who in America and Who's Who Among Physicians and Surgeons and Who's Who in Person and America's Young Men, several years ago.

Q. Dr. Belt, you are connected with the Belt Urological Group, is that correct? A. Yes.

Q. Does that group conduct any research into urological matters? A. Yes.

Q. Has that research been recognized recently?

A. Well, yes, sir; we got a blue ribbon for the best laboratory research at the last American Urologic Association meeting, which met in Los Angeles last month.

Q. Doctor, you are an urologist, is that not correct? A. Yes.

Q. How long have you been engaged in the practice of [225] this specialty? A. Since 1922.

Q. And what parts of the body are covered in the practice of urology?

A. The urinary and genital tracts, the tracts through which the urine flows and through which the seminal fluids flow.

Q. Does that include the prostate gland in a male human? A. Yes.

Q. In your practice, have you had occasion to diagnose and treat disorders of the prostate gland?

A. Yes.

(Testimony of Elmer Belt, M.D.)

Q. As such, have you had occasion to diagnose and treat carcinoma of the prostate in males?

A. Yes.

Q. Do you have any estimate as to the number of cases of that type that you have diagnosed or treated?

A. Oh, yes; I think I do. It is a little difficult to give an accurate figure of that group of cases but I imagine I have observed upward of a thousand cancers of the prostate in men.

Q. Doctor, in your practice, have you had any occasion to use or observe the use of hormones?

A. Yes. [226]

Q. Particularly the male hormone and methyl testosterone? A. Yes.

Q. Have you personally seen or treated any patients who have had adverse or injurious results from the administration of the male hormone?

A. Yes; I think I have.

Q. Could you recount to the court any specific examples of this, Doctor?

A. Yes, your Honor, I have in my care at the present time a man 48 years of age, a Doctor of Medicine, who is eminent in the field of nose and throat surgery in this area, who began taking methyl testosterone because of what he thought was sexual depletion, about eight months ago. He took material for two months. When he first noted difficulty in passing his urine, a symptom which he had not had previously, and he continued to take the material and his symptoms continued to grow worse. He

(Testimony of Elmer Belt, M.D.)

took it for a period of about four more months and then he discontinued it. But, with the discontinuance of the methyl testosterone, his symptoms of distress in urinating and difficulty of urinating did not cease, and so finally he came in to ask for an examination of his prostate, and he had a definite cancer of the prostate, which however was early enough to remove completely, and I removed it, and the section showed a very marked carcinoma of the prostate which involved about two-thirds of his prostate gland.

Q. (By Mr. Danielson): In your opinion, Doctor, did the administration of testosterone in any way influence this particular cancer of the prostate?

A. I think it very likely did, very definitely influenced it. [228]

Q. What are your reasons for your opinion there?

A. Well, in the first place, a full blown cancer of the prostate in a young man is relatively rare.

The decade in which cancer of the prostate begins to be fairly frequent is from 50 to 60. It is much more frequent in the decade of between 60 and 70, but a few cases are described as early as 45.

Q. What particular aspects of this carcinoma cause you to believe that the testosterone may have adversely affected it?

A. He did not have symptoms at all of urinary tract distress until he had taken this material for two months and then he began to have difficulty in urinating and then, subsequent urologic examination

(Testimony of Elmer Belt, M.D.)

showed that this growth was in a casing around the tube through which he had to urinate, so it was choking it down and I think it was because of the effect.

Q. Now, Doctor, do you have any opinion as to the normal incidence of carcinoma of the prostate in males, let us say, 50 years of age?

A. Recognized, the clinical carcinoma of the prostate in males 50 years of age is relatively rare. I would think that the incidence—again I find it difficult to name definite figures but what I can say is this: that patients who come to us with difficulty in urinating in the 50-year old group [229] of men, cancers of the prostate would appear probably in one out of 35 or 40 with those who came in with urinary distress, difficulty in urinating. Now, we see a very selected group of patients. They come to us because they have trouble in urinating, but those who prove to have cancer of the prostate at that young age are quite rare.

Q. What would your opinion be as to the age group of let us say 60?

A. It is more frequent. From 60 years on, about one case in 12 who come to us with urinary difficulty, the patient comes in and says, "Doctor, I am getting up at night to urinate four or five times, I find it difficult to urinate in the daytime, it is hard to start my stream," that group of symptoms will have one in 12 who will have cancer, while 11 will have what we call benign adoma of the prostate.

Q. What do you mean by benign?

(Testimony of Elmer Belt, M.D.)

A. Benign means kindly, of course, and the growth of the prostate which is not malignant.

All cases of prostaticism producing difficulty in urination are not caused by the same thing. Roughly, there are three big cases. One is the group of inflammatory diseases of the prostate, which simply causes the prostate to shrink and therefore closes the tube for passing urine.

The other, benign adoma prostate, which are tumor growths which do not spread from the locality to other areas and therefore [230] are benign. They may produce a lot of trouble but they don't spread.

And the third, cancer of the prostate.

Q. (By Mr. Danielson): Now, does the rate of incidence of carcinoma of the prostate increase in the next decade, let us say in men of the age of 70?

A. It does, a little, it increases a little in the next decade, but from 60 to 70 on or from 60 on, the figure of one in 12 obtains pretty generally.

Q. You have testified that you have had experience with the use of the male hormone, testosterone, in various patients. In your opinion, on the basis of your education and training, experience, research and study, do you have an opinion as to whether the use of methyl testosterone would accelerate the growth of an incipient or early carcinoma of the prostate?

A. Well, I think it would, but I would like to go back to that former question, if I could, which you asked about the incidence of the cancer of the prostate.

(Testimony of Elmer Belt, M.D.)

Q. Yes.

A. And I spoke about the clinical incidence. By clinical we mean the manifestation that the patient can recognize, that shows symptoms and then the doctor will find something wrong with the instruments, the hand, his fingers or eyes. [231]

Q. That is such as the difficulty in urinating?

A. Yes, sure, where the doctor puts a finger in the rectum and finds a lump or finds residual urine and so on, something that makes the patient sick and brings him to the doctor for attention.

But, now, when you ask about the incidence of prostatic cancer in man, there is another thing that just must be said, and that is that there is a large group of cases which are not clinical, in which no symptoms have been discerned by the patient or by the doctor in examining the patient, he doesn't even uncover symptoms that the patient hasn't noticed, or signs. But that patient may have a cancer of the prostate and it may be showing no trouble and it may be dormant and riding along and perhaps it never would cause any trouble.

Q. On that same point, what is the reason for this information you are now giving us?

A. That comes out of the pathological laboratory. You know, every doctor who has his eyes on his work and really wants to learn all he can about it asks for a post-mortem examination of every patient who dies under his care. Now, he may get a lot of rebuffs, but most people are understanding and allow that kind of thing and in general that causes

(Testimony of Elmer Belt, M.D.)

the accumulation of a body of knowledge which is helpful to all of us and in this particular problem it is particularly helpful. [232]

Now, we have made observations on that point which affect us all. Dr. Moore at Johns Hopkins, his was the first series of observations, and Dr. Moore formed the habit of taking men from 40 years on and carefully slicing the prostates thin, so thin that they were almost transparent little slices and then laying them over a sheet of opalescent glass and picking out the area where the cells seemed to be growing and make a microscopic examination of those areas, and Dr. Moore was actually able to see that in one patient out of three, from 50 years on, there were little clumps of cells which were definitely cancerous in those patients, and what the future history of that patient would have been if he had lived, no one knows. But, at any rate, here were these clumps of cells that showed microscopically, and they showed there with ever increasing frequency as the age went on towards 70 and 80, and so on.

Q. What do you call these little clumps of cells?

A. Nidus nodules or beginning areas of cancer growth. Now, that is the difference between a laboratory research project and a clinical research. Now, clinically, we can take a case of an ordinary practitioner to whom a patient goes just simply because he wants a general physical examination as a routine matter. That man is obligated to put his

(Testimony of Elmer Belt, M.D.)

finger in the rectum of the male and carefully feel the prostate. [233] Now, he cannot feel all of these areas, because it would take a microscope to discern them, but he can feel them as they begin to become dangerous and become together in large enough groups to see that there is a difference in tissue, that he can feel with his fingertip, and that is when it becomes clinical.

Q. Now, you say your personal research has confirmed this same phenomena, is that correct?

A. Yes, my personal observations. It is not hardly called research. In a way it is, I guess, but for all the years I have been in practice I have always carried out autopsies wherever I could and examined the tissues myself, personally, in the company with the pathologist whose profession it is, of course. But we have confirmed that relationship that Dr. Moore has shown, by our own personal observations. Many men have it. Once, Dr. Moore showed it to us.

Q. And this has been confirmed many times since then, is that correct?

A. Oh, yes.

Q. On the basis, again, of your training, education, study and research and knowledge of prostatic conditions, is it your opinion that these little nidus or little clumps of cells could, under proper environment, develop into a carcinoma of the prostate? [234]

A. Oh, yes. That is the whole significance of this work.

Q. In addition to the case that you have just

(Testimony of Elmer Belt, M.D.)

mentioned about the doctor who was presently under your care, have you seen any—are you aware of any other instances in which the administration of methyl testosterone has accelerated the growth or spread of a prostatic cancer?

A. Well, not methyl testosterone, but testosterone propionate. Actually, I guess the purpose of this inquiry—there isn't enough difference to make it worth while, but you said methyl testosterone?

Q. That is correct.

A. And I saw a case in which I am sure that the androgen which was administered, which was testosterone propionate, certainly caused a very great increase in prostatic cancer over what it would have been without it, without the administration of this material.

Now, this patient was a man of 57 who was taken sick, as far as he was concerned his first evidence of trouble was in October of 1940, and he went to his doctor in San Francisco in October of 1940, who made an examination and found a carcinoma of the prostate.

Now, the patient was run down and sick looking and felt desperate and in addition to his urinary complaints, and so, the doctor gave him testosterone propionate in the hope that [235] it would build him up and continued to give him testosterone propionate by injection in the muscles, twice a week.

And the patient came to Los Angeles in September of 1941, eleven months after this kind of treatment had been started, and he came to us, and Dr. Huggins work, which showed the very definite rela-

(Testimony of Elmer Belt, M.D.)

tionship between carcinoma of the prostate and the androgens as an increaser of cancer of the prostate, and the estrogens as a depresser of cancer of the prostate, had come out in April of 1941 and I was familiar with that work. And so I took this old gentleman off of testosterone propionate and substituted the estrogens, the female hormone, and he felt a little better, but he went on to his death and when he died—and the reason why I think that the androgen that was given to him produced a remarkable effect is because when he died, our post-mortem examination showed an extent of metastasis which is beyond anything I have ever seen, and we have shown the pictures to many physicians and no one has ever seen a case of a cancer of the prostate which was so extensive in its spread as this particular patient's, who had the androgen testosterone propionate administered to him for a year.

Q. You say you have had pictures made of that development?

A. Yes, I brought them along.

Q. Would it assist you in explaining it for us by showing [236] those pictures, Doctor?

A. Yes, I think it would.

Mr. Danielson: With the permission of the court, could we have this slide shown?

Will you step down, Doctor, and there is a pointer you will be able to use.

The Witness: Well, I have several slides here which I think will clarify the subject, if the court wishes.

(Testimony of Elmer Belt, M.D.)

The Court: Go right ahead.

The Witness: The prostate is the size and shape of a chestnut in a normal fellow, and if you take a chestnut and bore a hole from the base of the chestnut through to the apex, you would have the urinary passage through which the urine flows. This spreads itself on the back of the bladder and this prostate is on the bottom of the bladder. The bladder would be here (indicating on slide).

Our urine flows from the bladder through the prostate, to emerge through this urethra, and anything that increases the bulk of the prostate takes its toll of interfering with freedom of urination, by pressing on that canal that runs through that prostate. Now, benign nidus do that and so do cancers.

The cancer nodule may be very advanced before it actually begins to exert pressure on this canal and the virtue of a rectal examination frequently in man of the cancer age, from [237] 45 on, the virtue of frequent rectal examinations is that a small nodule like that, before it is exerting any pressure on the canal and producing symptoms, can be picked up. If you find a little nodule like that, or two or three nodules or a single nodule with the general firmness of the gland, we can we can take that out surgically with a very good chance of complete recovery of the patient and a disappearance of his cancer so that he won't have any trouble again. And it was this kind of a thing that we found in our doctor that

(Testimony of Elmer Belt, M.D.)

I have told you about, and I hope that we have cured him.

But when the cancer advances into these lymph nodes around these things which are seminal vesicles or spreads into the bony structure of the patient, then we don't save him by any operation.

Now, this is the kind of a thing, the way a prostate looks after you get it all out. Here (indicating) was the urethra at the apex of the prostate. That is upside down. It is what I saw in that doctor, but it is the way it appears as you are working on the patient, and here is the seminal vesicle and here is the ampulla.

This was his little cancer nodule, and these were cancer nodules, too.

That patient made a complete recovery.

Here is the old gentleman that I spoke of—well, a 57-year old patient, he is not so old except in the fact that he [238] was so near death. His cancer of the prostate had extended in this peculiar way, and it involved all of his prostate and then it had extended in a carus or casing, clear around the rectum, which I have never seen happen in any other patient.

This is the rectal outlet here, and there it has gone clear around, the rectum making sort of a sleeve, with cancer tissue around it and then invading the urethro-perineal tissues, that is to say, behind the whole back of the man, behind the peritoneum up into his liver and surrounding his intestines, and that is the liver we see there through

(Testimony of Elmer Belt, M.D.)

the opening on the bottom and will turn that liver up out of there, and you see these tremendous masses of cancerous tissue throughout that specimen.

And lifting the liver out and putting it in a big basin, the size of the liver is seen to be five times the normal liver size.

And when you cut that liver in two, you can see that it is just completely replaced by these great cancer nodules.

Now, it is not infrequent for cancer to extend into the liver, but to occur completely in that way and to throw so many metastasis throughout this elderly man's body is the unusual thing.

You see, that is almost a complete replacement of that vital organ with cancerous growth, and the very magnitude of [239] the growth is the thing that makes me feel that the androgen administered to him was in such magnitude, because of the two things taken together, a case in which testosterone was administered for a course of a year, which also showed more metastasis than anyone in this area had ever seen from this disease—now, this little chart. In a way, I really ought to leave this for Charlie Huggins, but perhaps I can clarify what he is going to say to you, by telling you of his work. He might be too modest.

Dr. Huggins has taken two immature prostates in dogs and has given them injections of testosterone propionate. These were little puppies, and the zig-zag rising curve here shows that in a period of six days, on 10 milligrams of testosterone propionate

(Testimony of Elmer Belt, M.D.)

daily, these prostates came to rapid maturity, the puppies had adult prostates at the end of that six-day period.

Now, the opposite effect is shown here on the volume of the seminal fluid, in the giving of the female hormone estradiol benzoate.

Here is a fullblown male dog, with lots of sexual pep and vigor, and the dose of female hormones begun to shut off that progress of seminal fluid, drops down nearly to zero and since then, when the female hormone is stopped, bang, up goes the activity of the prostate and seminal vesicles again, showing the tremendous depressing effect of the female [240] hormone on the dogs' prostate, seminal fluid and prostate.

And this is the same sort of a grouping in another case. Dr. Huggins has done that again and again. This was a very interesting corrolary of that same thing.

Here is a bilateral orchectomy. He took off both testicles from this dog, and the dog immediately drops in all activity, of both prostate and seminal vesicles, they just shriveled up and quit.

Then he began injections of 25 milligrams a day of testosterone propionate and immediately the dog's prostate makes a recovery back toward normal. And the minute he stops giving that material in the ordinary sized dog, the prostate shrivels up again and goes back to nothing.

Now, here is a very interesting experiment which combines two things. The dog is castrated and he

(Testimony of Elmer Belt, M.D.)

drops to nothing so far as his prostate secretion is concerned. He is given testosterone propionate in 10 milligrams daily amounts and he starts on his upward climb toward normal.

Then, in addition to this testosterone propionate, he is given stillbestrol in a very small amount, 2/100 of a milligram, and it doesn't do anything for that that can be seen on the chart.

Then he gives a tenth of a milligram and he gets a pause. Then he gives 2/10 of a milligram and the rise levels off. [241]

So, 2/10 of a milligram of stillbestrol daily just about neutralizes 10 milligrams of testosterone propionate daily. The two things are chemical antitodes.

Then he gives 4/10 of a milligram and the curve begins to go downward, the curve of testicular activity of the prostatic activity and then he gives 6/10, and the curve of prostate activity goes clear down to zero again.

The point of it is that 6/10 of a milligram of stillbestrol a day counteracts completely 6/10 milligrams of testosterone propionate, and the experiment shows that the two are physiological opposites.

About the time that Dr. Huggins had made these observations work came out to show that acid phosphatase, one of the enzymes in the human body, that the body became flooded with this acid phosphate in cancer of the prostate, in advanced cases of cancer of the prostate the patients had a large amount of this acid phosphatase. Dr. Huggins

(Testimony of Elmer Belt, M.D.)

knew that acid phosphatase was made in the prostate, and he felt, then, that this would be a good criterion to show if stillbestrol would cause a deleterious action on cancer of the prostate, make the patient better.

So, he examined some of the nodules of metastatic cancer in distant places, and found that they were parts of these acetate phosphates.

Now, when he gave stillbestrol as a result of this observation [242] to cancer of the prostate patients, the acetate phosphatase dropped away down here to zero and with a corresponding increase in well being on the part of the patient and correspondingly, when he took off both testicles and prevented the patient from being flooded with his own testosterone, the acid phosphatase again dropped to normal.

Now, these patients improved in direct correspondence to the dosage of stillbestrol that they were getting.

This complicated looking curve simply shows case observations and shows that in a grouping, it happened to be 85 patients in this total group with cancer of the prostate, when treated with still bestrol, they all suffered a gain in weight, they all suffered a rise in their red cell count and haemoglobin and all underwent a correspondingly great increase in well being.

Now, this work of Dr. Huggins has shown us definitely that testosterone propionate, that is the

(Testimony of Elmer Belt, M. D.)

male hormone which the male makes in the natural course of his ordinary existence, is a stimulating factor for carcinoma of the prostate and helps carcinoma to become widespread and probably to form and to keep going, and that, on the other hand, if this testosterone propionate is stopped either by neutralizing it with stillbestrol or by removing the source, by taking off the testicles, that for a time the patient goes into a sort of well being which was unprecedented in our knowledge [243] of cancer prior to this work. We had never seen anything like this.

Of course, unfortunately the body, like it does to all things, adjusts itself to these differences and in time the patient is again swamped with this cancer and goes to his death.

Although there are on record cases which have gone along since 1940, now, without any evidence of cancer, after the cancer has once been overcome by stillbestrol or by abolition of the testicles or by both, taken together. There was an ever-increasing number of such cases which have been apparently cured, although no doctor speaks of cancer as being cured. We know too well that even after 25 years, a cancer which has apparently been cured and forgotten, suddenly blossoms out and overwhelms the patient.

There are many more things about this that are unknown, than are known.

Q. (By Mr. Danielson): Now, Doctor, in the case of these small clumps of cells that you men-

(Testimony of Elmer Belt, M. D.)

tioned that are determined by pathological examination of the prostate or by laboratory examination of the prostate, you say on the basis of your opinion, would testosterone administered to such a person affect the growth or development of these clumps of cells?

A. I believe that it would hurry it, yes, [244] probably light it up and cause it to become active instead of dormant.

Q. Now, specifically, do you have an opinion as to whether testosterone in the form of 25 milligram tablets, methyl testosterone administered one tablet daily for an indefinite period of time—could that have such an effect, in your opinion?

A. I think it well could.

Q. Would 10 milligram tablets of methyl testosterone, again administered one daily for an indefinite time, or three daily for 10 days, followed by one daily for an indefinite time, have such an effect, in your opinion?

A. Yes, I think this substance is dangerous in that respect, that it could aggravate a carcinoma of the prostate or bring it from a dormant state into active state and destroy the patient.

Q. Are you familiar with methyl testosterone in the form of linguets, Doctor?

A. Yes, indeed.

Q. In your opinion, could linguets containing five milligrams of methyl testosterone, each, administered at the rate of three to four linguets per day, for an indefinite time, have such an effect?

(Testimony of Elmer Belt, M. D.)

A. Yes.

Q. Doctor, in your opinion, is there any difference in the therapeutic effect of testosterone in its different forms? [245] By that I mean methyl testosterone, testosterone propionate and so forth?

A. Yes, there is a little difference in their therapeutic forms, in their action.

Q. Could you elaborate on that, please?

A. Oh, it is pretty difficult to say definitely what the difference is. Testosterone propionate tends to be held by the tissues a little better than methyl testosterone, a larger proportion of the methyl testosterone appears in the urine and is thrown out, but I think that the body metabolizes both of these substances into the same thing, in its use, with time, and that one is a little bit more wasteful than the other, and that is the only difference.

Q. Well, as the body uses these two drugs, however, is the use the same?

A. Yes, the body converts them into the same thing.

Q. Now, Doctor, you have mentioned that you have used methyl testosterone or testosterone in some of your treatment. Are there any instances that you know in which methyl testosterone or testosterone can have a good effect?

A. There are many instances in which it is a drug which is very valuable.

Q. What precautions, if any, are necessary prior to such use?

(Testimony of Elmer Belt, M. D.)

A. We have several tests for the presence of cancer and [246] they should be applied, cancer of the prostate I am speaking of now. One is the digital examination that I have tried to make clear.

Another is the level of acid phosphatases in the bloodstream which I mentioned. And then there are two other tests which are very recent, one a test of the proteins of the blood which shows the presence of the cancer or the absence of it, which is useable before any other clinical test can show the presence of cancer, that should be applied. And still another test, which is also a protein, a blood protein test.

Q. You feel that such precautions are a prerequisite to any testosterone therapy then, is that correct?

A. That is right, except in groups where cancer of the prostate is not liable to occur and by that I mean the cases in which testosterone is particularly valuable, or the groups of young individuals who show a definite endocrine deficiency in regard to testosterone and who need the substance in the normal process of their growth and development.

Q. How is it possible to determine whether or not there is such an endocrine deficiency?

A. There is a clinical method, observation of the patient. You would recognize an endocrine deficient person if he sat here, possibly, if you were familiar with it, through his changes in his growth and certain texture of the [247] skin and so on. That would be the clinical type of thing.

(Testimony of Elmer Belt, M. D.)

Then, there is the laboratory work. We have what we call the 17 ketosteroids, which appear in the urine in certain quantities and the amount there can be measured, and if they are measurably low, it means that a deficiency exists in the hormone-producing structures of the body.

Q. It is easily or relatively easily recognized in groups such as the first—I am referring now to the eunuchs and eunuchoid groups?

A. That is right. During the war, the last war, we had a large group of fellows who lost their testicles from land mines. On land mines they stubbed their toe against them and the thing explodes, and on the upward explosion it carries off their testicles because they are projecting just a few millimeters beyond the level of the thighs, and they are ripped off, and those boys have to have this help, and testosterone linguets, testosterone propionate, of course, are just invaluable remedies. They bring this lad, who had been pale and lethargic and disinterested and useless into active life so that he cannot be discerned from anyone else.

Q. In a person who is apparently normal physically, who has all of the apparent physical parts of his body, what examination would be necessary to determine whether there is such an endocrine deficiency? [248]

A. Well, the 17 ketosteroids might show it, the application of that test. The principle of that is everyone produces more and much more testosterone propionate than he needs, at any given age

(Testimony of Elmer Belt, M. D.)

of his life. The testicles overwork. So do the ovaries, for that matter. And an amount of this material, testosterone propionate, on the one hand, and estrogenic substances on the other in the female, is thrown out in the urine constantly and that is measurable, it is recoverable, and you can see the extent to which that loss of substance occurs and in that way you can measure whether or not the testicles are producing the normally expected overflow of this material.

Q. Now, those examinations you have just mentioned, do they require special training, Doctor?

A. Oh, yes, they do.

Q. Are there any subjective symptoms of this male hormone deficiency which a layman could recognize and accurately use to diagnose such a condition?

A. Oh, gosh, I wouldn't think a layman could know. He might confuse almost anything with loss of what he thought was his normal quantity of hormones. If he just began to feel tired and run down or if his tennis arm was not satisfactory, or if he made too many strokes in his game of golf, he might decide that he was passing into the climacteric and therefore should take a few testosterone linguets. [249]

Q. Doctor, in your experience, has such been the case?

A. Oh, yes. We are taking people off of this stuff all the time.

(Testimony of Elmer Belt, M. D.)

Q. And what, as the result of your studies, has caused them to start using this preparation?

A. They read in the newspapers they must. We have a gullible American public.

Mr. Danielson: No further questions. You may cross examine.

* * *

The Court: I want to get one thing clear. I have got to analyze this thing the best that I can as we go along. I don't know what the cross-examination may develop. But at this stage I would like to know this, as your opinion, you understand. Supposing after a careful examination of a subject, no nodules or other indications or other incipient cancer are found. Do you think it would still be dangerous or conducive to the development of cancer in the prostate to take this hormone, testosterone? [251]

The Witness: Yes; actually, it would.

The Court: Then, tell me for what reason and upon what you base your opinion.

The Witness: Because you can't feel all the areas that might be involved.

The Court: You mentioned some other test in addition to the digital test.

The Witness: Yes. If the protein test was made, it would be less likely to cause trouble, but even this giving should be all controlled by relative frequent examinations. I think, if testosterone propionate is used in an individual in the cancer group, he should have the benefit of these tests

(Testimony of Elmer Belt, M. D.)

which are necessary to show the presence of early cancer, frequently, at least twice a month, as a control.

The Court: In your judgment, what would be the effect on the patient by reason of the administration of this hormone, in the dosages that have been mentioned here, 25 milligrams daily, and then perhaps tapering it off after the first week and so on, and running for a period of two or three months? What, in your opinion, would be the effect on the patient? Would it have a deleterious effect and, if so, why?

The Witness: It could be a deleterious effect through stimulating a cancer which was latent or dormant.

The Court: Supposing no cancer came into the picture.

The Witness: It need not necessarily be deleterious then. [252]

The Court: Would it be beneficial or stimulating or rejuvenating or invigorating?

The Witness: There are a few special cases in which testosterone propionate is stimulating and of value over short periods of time, and that applies to methyl testosterone taken by mouth, too. What I am pleading for in this case is that it be adequately controlled, with careful observations, in order not to run the patient into danger, because the good advantage this material does is out of all proportion in relation to its harm. The amount of

(Testimony of Elmer Belt, M. D.)

potential harm it has is much more than the good it can do if used unbridled. [253]

* * *

CHARLES HUGGINS, M.D.

called as a witness by the government, being first duly sworn, testified as follows:

Direct Examination

By Mr. Danielson:

The Clerk: Your full name?

A. Charles Huggins.

Q. (By Mr. Danielson): What is your address and present occupation, Doctor?

A. My address is University of Chicago, Chicago, Illinois, and my present occupation is Professor of Urology at the University of Chicago.

Q. Of what schools are you a graduate, giving the years and degrees, please?

A. I am a graduate of Acadia University in Canada, Bachelor of Arts, 1920, a graduate of Harvard Medical School of 1924, Doctor of Medicine; I have honorary degree of Doctor of Science, of Acadia University, 1956; I have an honorary degree, a Master of Science from Yale University, 1947.

Q. What post-graduate training have you had, Doctor?

A. Well, I have had three years of training in surgery at the University of Michigan, 1924 to 1927.

(Testimony of Charles Huggins, M.D.)

Q. Are you a member of any medical or scientific societies?

A. I am a member of the National Academy of Science, member of a number of professional societies, for example the American Urology Association, the American Association of Genito-Urinary Surgeons; American Medical Association.

Q. Yes. Those are representative societies, is that correct? There are others?

A. Well, let us put in the American Association for Cancer Research.

Q. Do you now or have you had any hospital appointments, Doctor?

A. I am the head of the urology department at the hospital of the University of Chicago and have been so for 20 years.

Q. And you do hold a teaching appointment at the present, at the University of Chicago?

A. That is correct.

Q. Have you held any other teaching appointments?

A. I have been instructor in surgery at the university of Michigan.

Q. Have you ever practiced medicine, [257] Doctor?

A. I practiced medicine since 1924.

Q. And what is your specialty, if any?

A. I profess to practice and teach urology.

Q. Have you written or published any articles on medical or scientific subjects?

(Testimony of Charles Huggins, M.D.)

A. I have published approximately 150 papers on urological and scientific subjects.

Q. Has any of them related to the use or function of the male hormone?

A. Since 1938, our work has been almost exclusively related to the male hormone and its action in normal and cancerous individuals.

Q. Has some of these papers from this research related to the function or effect of the male hormone upon prostatic cancers?

A. We have published about 20 papers in this field.

Q. Doctor, have you had any personal recognition for your work in this field?

A. I have had the honor of being awarded several prizes by national scientific bodies, for this work.

Q. Would you name a few of these, please?

A. Well, in 1942, I was awarded the Judd prize by the Memorial Hospital for treatment of cancer in New York City. This was a prize of \$1,000.

Q. Have there been some other such recognitions, [258] Doctor?

A. In 1943 I received a Mayer award of the National Academy of Sciences, for what they considered the most significant work in cancer in the previous five years.

Q. Have there been any others?

A. In 1948 I received an award of \$1,000 from the American Urological Association for what they called outstanding research in the function of the

(Testimony of Charles Huggins, M.D.)

male genital tract; and in 1948 I received a septennial prize of \$3,500 from the American Academy for Arts and Sciences in Boston, Massachusetts, given for what they call outstanding contributions to the treatment of men with difficulties in the genito-urinary field.

Q. Have there been any other such recognitions or prizes or awards, Doctor?

A. I think this is perhaps enough, sir.

Q. Thank you very much.

You are familiar, are you, Doctor, with the effects of the male hormone on the human body?

A. Yes.

Q. Are you familiar with the effect of the male hormone testosterone on males in their late forties or in their middle age?

A. We have studied males of many ages, young and old, both human and animal, and I think I have a reasonable familiarity [259] with men in their late forties as well.

Q. Are you familiar with the effects, then, of the male hormone on male humans with a male hormone deficiency?

A. We have not seen many patients with a male hormone deficiency. I think that it is a very rare condition, but we have treated possibly 30 patients in the last 11 years with male hormone deficiency.

Q. Under what conditions does a male hormone deficiency occur in a male human?

A. We think in human beings, male hormone deficiency occurs more commonly in two states, one

(Testimony of Charles Huggins, M.D.)

which we in medicine call hypogonadism, where the male sex hormone is produced in small amounts or is not produced at all, a congenital state; second is the castrate male, where the testes have been removed as a result of operation or accident. These are the chief types of male hormone inadequacy.

Of course, in very grave states of illness, such as an advanced tuberculosis, there is a hormone deficiency not related to congenital causes or to accidental or purposeful removal of the testes.

Q. Could you give us an opinion as to the incidence of this latter situation in the advanced case of tuberculosis?

A. I think that in very gravely ill patients, bed-ridden patients with advanced disease, it is rather common. But I do not think that it occurs in quasi-normal individuals, [260] people who are able to be up and around, for example.

Q. Do you have an opinion as to the incidents of hypogonadism in human males, Doctor?

A. In a hospital population, we see those about twice in a thousand admissions to the hospitals, so that it is an extremely rare condition.

Q. That would be two out of a thousand admitted to the hospital?

A. Yes, as a maximum, two. Perhaps one per thousand, between one and two per thousand patients coming to the hospital with disease have hypogonadism.

Q. And, Doctor, what do you mean, precisely, by hypogonadism?

(Testimony of Charles Huggins, M.D.)

A. Hypogonadism is usually—it is not always—a congenital state wherein bodily growth is reasonably satisfactory but in which the external genital organs remain undeveloped, the secondary sex characteristics remain undeveloped; the male will speak with a soprano voice, he will have no growth of hair on the face, on the chest or in the genital region. There is, in these patients, failure, complete failure of the erections of the penis, a complete failure of ability to have sexual relationships. This is hypogonadism.

Q. As to the definition of the word, then, hypo I understand means below or under, or below normal, is that correct?

A. That is correct. [261]

Q. And the word gonad refers to the——

A. Testes.

Q. I see. Now, is this situation a transient condition or is it a condition that is with a person permanently?

A. This is a condition that is permanent, except that it can be adequately treated by certain hormones.

Q. Now, Doctor, do you have an opinion as to the incidence of castration in human males?

A. Castration in patients, as they present themselves to a clinic, is quite rare, except in patients who have had castration to eliminate the male sex hormone, which is a factor in cancerous prostate.

Q. Do you have an opinion as to whether the incidence of castration is as great as that of hypogonadism?

(Testimony of Charles Huggins, M.D.)

A. Until 1941 we practically never saw a castrate in the clinic.

Since 1941, since our work on the damaging effect of the male sex hormones on certain cancers of men, since this has been widely adopted, we see now considerably more patients with castration than we saw before.

Q. And in referring to these persons among persons admitted to the hospital, these are persons who are already ill for some reason or other, is that not correct? A. That is true.

Q. Coming for treatment. Now, Doctor, you have mentioned [262] that in connection with hypogonadism there can be effective treatment with hormones. Would you explain that, please?

A. Well, by giving androgens, the male sex hormone, one can restore the sexual drive of these people, one can restore the secondary sex characteristics. Of course, one cannot restore the testes as such. And that is the standard treatment.

Q. Doctor, do you have an opinion as to what would be the daily requirement of androgen, the male hormone, to produce this effect on a hypogonad?

A. We treat patients with one of two types of hormones, either injections of testosterone propionate, and there the daily dosage is about 5 to 10 milligrams; and another way of treating these patients is by methyl testosterone, by mouth, and there the daily dose is 10 milligrams by mouth.

Q. Is the 10 milligram dosage of methyl testos-

(Testimony of Charles Huggins, M.D.)

terone adequate to convert the hypogonad into an apparently normal male?

A. That is correct. 10 milligrams will restore, from the standpoint of secondary sex characteristics, a hypogonad patient, to normal.

Q. And will enable him to maintain that status?

A. They will maintain it as long as the methyl testosterone is administered. [263]

Q. What dosage would be required for the same purposes, in the case of a castrate, Doctor?

A. The same dosages.

Q. 10 milligrams daily of methyl testosterone would be effective?

A. We think the 10 milligrams of daily administration by mouth of methyl testosterone is equivalent to what a normal healthy young male is producing in his own gonads.

Q. Could you give us a comparative effect, a comparative potency of injected testosterone propionate and orally administered methyl testosterone?

A. Injected testosterone propionate is roughly twice as strong as methyl testosterone taken by mouth. [264]

Q. Doctor, you have mentioned that these dosages of 10 milligrams daily of methyl testosterone are adequate to produce these wonderful and beneficial effects on hypogonads and castrates. Do these drugs produce any toxic effects on the human male?

A. We must divide the human male into well patients and ill patients. These androgens are very powerful agents. One cannot take, in my opinion,

(Testimony of Charles Huggins, M.D.)

androgen in the same way that one can take a drink of water or a piece of candy. You must take them with impunity. These things, when they are given, definitely cause derangement of the organism. For example, a person taking methyl testosterone or testosterone propionate thereby inhibits his normal mechanism for producing the male sex hormones.

Q. What would be the effect of that?

A. Well, this is rather complex physiology. There is a system called the male genital system consisting of the pituitary and the testes and the secondary sex characteristics. If one takes, administers or has administered to him, one of these agents, that deranges the factory mechanism. If one takes methyl testosterone or any other testosterone, that will make the pituitary gland function at a low level so that, when a persons stops such administration of the drug, then the pituitary functions at a low level for a number of months.

Q. Is that harmful or beneficial?

A. That is harmful. A second harmful effect of a [265] normal person taking testosterone is that it cleans out the testes of the germ cells, the spermatozoa, so that a patient, therefore, is unable to fertilize a female.

Q. That is, it cuts down on the production of sperm, is that right?

A. It cuts down very marketedly on the production of sperm. These are the effects in a normal person. In an ill person other undesirable effects are manifested.

(Testimony of Charles Huggins, M.D.)

Q. Generally, without great detail, what would be the nature of such effects?

A. The clearest cut instance is activation of cancer of the prostatic gland.

Q. Doctor, by androgen you refer to methyl testosterone and testosterone propionate, is that correct?

A. Substantially correct. There are other androgens. Androgen and the male sex hormone and testosterone may be considered, roughly, parallel, synonymous.

Q. Is androgen a generic term which includes these others?

A. It includes all drugs or chemicals which can cause secondary sex characteristics in males.

Q. Doctor, you have mentioned about these dosages which have the beneficial and toxic effects on abnormal and normal humans. Can you tell me whether you have an opinion, based on your education, training, experience, study and [266] research, as to whether tablets containing 25 milligrams each of methyl testosterone, taken one each day for a definite period, would have these effects on a male human?

A. 25 milligrams a day would certainly have these effects.

Q. Either the good or the bad, is that correct?

A. That is right.

Q. On the same basis, Doctor, of your training, and the sum total of your knowledge, do you have an opinion as to whether 10-milligram tablets of

(Testimony of Charles Huggins, M.D.)

methyl testosterone, taken one each day for a definite period, would have these effects?

A. It would have the same beneficial and, also, harmful effects.

Q. And, by the same token, a larger dosage of the same would have more pronounced effects?

A. That is correct.

Q. Do you have an opinion, on the basis of the sum of your knowledge of this subject, as to whether 5-milligram linguets of methyl testosterone, taken at the rate of two linguets three times daily, would produce such effects?

A. My opinion is that they would produce such effects.

Q. Both the good and the bad, is that correct?

A. That is correct.

Q. Doctor, you have mentioned that you are familiar with the use of testosterone in the treatment of hypogonads [267] and castrates, as well as normal people. In instances of male hormone deficiency, are you familiar with the symptoms of such a person?

A. That is right; I am.

Q. On the basis of your training, education, experience, study, research and the sum of your knowledge, do you have an opinion as to whether the use of methyl testosterone would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of the hair, muscular development and depth of voice?

A. I do.

Q. What is that opinion?

(Testimony of Charles Huggins, M.D.)

A. The opinion is slightly complex since it has different effects, quantitatively speaking, in hypogonad people as opposed to the effects in a normal healthy male. In a child, tremendous growth of the penis, and secondly, sex characteristics, change in the depth of the voice, growth of the hair on the face and on the chest, occur. In hypogonadism and in children these effects are very marked, indeed. These effects are, quantitatively, very much less in a normal healthy male.

Q. In a castrate is there any less effect, or any such effect?

A. In a castrate it depends whether the castrate was—whether the procedure of castration was done at an early [268] stage, before puberty or after puberty. In general, androgen stimulates a castrate very much as it does a child or a patient with hypogonadism. If castration has been done late in life, say, for example, at the age of 30 or 40, it has less effect in restoring hair and depth of voice than in a young person.

Q. Do you have any opinion, Doctor, as to how early an age a child would be so affected by androgen therapy?

A. From the age of one year on there would be tremendous growth; perhaps before one year. I don't think anyone has given androgen to a child of less than one year.

Q. And a small boy would be so affected, is that right?

A. To give androgen to a child of five, ten or

(Testimony of Charles Huggins, M.D.)

twelve, will make a tremendous sex drive, growth of the penis and desire to have sexual relationships.

Q. Could it render him sexually mature at such an age?

A. It will render him sexually mature at such an age with the exception that sperms are not produced. They will render a child sexually mature at the age of two years.

Q. Doctor, again on the basis of the sum total of your knowledge of this subject, do you have an opinion as to whether androgen therapy, the use of methyl testosterone, would correct the lack of sexual power in impotents?

A. Impotence is a rather complex situation, too. It occurs for two reasons. In general, we classify impotents [269] as psychogenic, which accounts for 95 per cent of the patients we see with impotence in normal healthy people, and the second classification is a deficiency of male sex hormones. The castrates, as a result, are impotent. The hypogonad patients are by function impotent. The effect of testosterone on impotence depends on the classification of the disease. If it is due to a hormonal deficiency, then testosterone will restore impotence to potency. On the other hand, unfortunately, 95 per cent of the patients that we see, or perhaps fortunately, in the clinic have psychogenic impotence.

Q. Just what do you mean by psychogenesis?

A. That is medical jargon. Psychogenic impotence is impotence where there is no deficiency of male sex hormone production, where it is believed,

(Testimony of Charles Huggins, M.D.)

for functional reasons, such as overwork, psychiatric conditions, neurathenia and things like that, a person is unable to have intercourse with a female. In this type of impotence the administration of androgen has no effect, and this was discovered in our clinic, so we know about these things.

Q. You say this was discovered in your clinic?

A. That is right, that androgen had no effect.

Q. Was some research conducted which produced this information there?

A. Yes; we studied a large series of patients with impotence of both kinds, both hypogonadism and the common [270] type of impotence, the functional impotence and the psychogenic impotence, and in the common type of impotence it had no effect. In hypogonadism it had spectacular effects in restoring.

Q. Your opinion, then, is based on actual clinical research as well as study, is that right?

A. It is based on clinical observation and it is fortified by publications in scientific literature.

Q. Doctor, again on the basis of the sum total of your knowledge as to this subject, do you have an opinion as to whether the use of the male hormone would relieve and postpone many conditions associated with middle age and improve the sense of well-being?

A. I am not quite sure that I have a correct understanding of "the many conditions associated with middle age." For example—is that what you mean?

(Testimony of Charles Huggins, M.D.)

Q. No. To put it conversely, Doctor, do you know of any conditions normally associated with middle age which will respond favorably to male hormone therapy? A. I know of none.

Q. Do you know whether the administration of methyl testosterone would improve the sense of well-being in otherwise normal persons of middle age?

A. A sense of well-being is, in very large part, a matter of the psychology of the patient. I can very well see how, if a person had confidence in this or that agent, if he [271] was taking this or that, it would in all likelihood make him feel better. Whether the belief was founded on a rational basis or not doesn't make any difference; he would be going to feel better. That is why religion flourishes.

Q. If I may interrupt you there, under those circumstances, would this result of well-being be due to a physiological condition or a psychological condition?

A. It would be due to a psychological condition. If a person were healthy, then it would certainly be due to a psychological condition.

Q. Again on the basis of the sum of your knowledge of this subject, do you have an opinion as to whether the use of methyl testosterone, the male hormone, would constitute an adequate treatment for flushes, sweats and chills, impaired memory, inability to concentrate on activities, a tendency to evade them, nervousness, depression, general weakness and lack of physical strength?

(Testimony of Charles Huggins, M.D.)

A. I, categorically, deny it would have any effect on all of those with the possible exception of flushes, and that is slightly complex. That is a technical term and requires further elucidation.

Q. In what situations might the effect on flushes take place?

A. The ordinary bashful girl has flushes but that type of flush is not germane to the discussion, in my opinion. [272] Patients, people, most commonly women, after the cessation of female hormone production, get something which is commonly known as flushes, hot flushes, both by physicians and the patients. In these hot flushes the patient has a sensation of a wave of heat passing through the body, followed by profuse perspiration, which he usually removes with a handkerchief or a turkish towel or something of that sort.

Q. May I interrupt you there? You say "he usually removes."

A. That she usually removes. I am glad to be corrected on that because this type of flushes which I have just been discussing, wherein a woman will mop her brow or face, we do not see in men. This, we think, is important evidence that physiologic cessation of hormone production does not occur in the human male.

Q. At any age? A. At any age.

Q. Regarding, again, the aspect of flushes, would there be any possible effect in the case of a castrate?

A. A castrate usually will have flushes, and there methyl testosterone will stop the flushes. A

(Testimony of Charles Huggins, M.D.)

person with hypogonadism usually will not have flushes, and I have never seen a normal person with typical flushes that a menopausal woman has, a woman after the age of approximately 45 to 50, where menstruation ceases, where female sex hormone ceases. [273]

Q. Are you referring to the period which is sometimes referred to as the female climacteric?

A. I am referring to the female climacteric.

Q. Now, Doctor, on the basis of the sum of your knowledge of this subject, do you have an opinion as to whether the use of methyl testosterone would result in improved physical and mental work and exert a tonic action, resulting in renewed vigor?

A. I have never seen any improvement in muscular or mental capacity in a normal male. In hypogonad patients, boys and young men, in whom the testes have never developed, it will cause an increase in muscular strength. Testosterone has no effect on the mind, on mental work.

Q. Would that apply to castrates as well as hypogonads?

A. A person, a castrate, in well-advanced adult life, let us say a male castrate after the age of 30, has no decline in muscular strength. He has no decline in mental ability.

Q. Again on the basis of the sum of your knowledge of this subject, Doctor, do you have an opinion as to whether the use of methyl testosterone would impart a better attitude towards social life and cause nervousness, exhaustion and melancholy to disappear?

(Testimony of Charles Huggins, M.D.)

A. I deny all of those categorically, that is, to state it in better English, I deny the effect of methyl testosterone in alleviating melancholy and these other symptoms that you [274] just read.

Q. Doctor, after these symptoms which we have just enumerated—you mentioned that you are familiar with the symptomatology of a person who is deficient in male hormones. Are these the symptoms of such a person?

A. They are not.

Q. Do you know whether they are the symptoms through which a normal male will pass in his forties or fifties?

A. A normal male does not pass through the symptoms as a result of gonadal deficiency and so he doesn't have the symptoms anyway.

Q. Are they the symptoms, just generally, of any other diseases or conditions?

A. This is a very complex question. Most patients whom we see with melancholy, lack of concentration and that sort of thing—the physician will find the average patient has it as a result of psychoneurosis or a functional nervous state.

Q. Do you have an opinion, Doctor, on the basis of the sum of your knowledge of the subject, as to whether there is such a phenomenon as male climacteric or male menopause?

A. That has been alluded to and described by some physicians but with this view I am completely in disagreement. I do not believe that there is a male climacteric.

(Testimony of Charles Huggins, M.D.)

Q. What is your reason for that opinion, [275] Doctor?

A. The phrase, "male climeractic" obviously is supposed to be identical with or analogous to the female climeractic in the female. In the female the ovary ceases to produce germinal cells and, second, the production of female sex hormone falls to a very low level or vanishes. The production of germinal cells in the male does not regularly occur, even in a very advanced age in the human male.

Q. Do you mean the cessation?

A. The cessation of production.

Q. Then old males will still produce sperm, is that right?

A. Yes; old males generally have sperms and are capable of becoming fathers.

Q. How about the production of testosterone?

A. The male sex hormone, likewise, while it may be reduced in part in old age, and no doubt is, definitely is produced in a healthy person.

Q. Doctor, some time back you mentioned that there are some beneficial and toxic effects of the use of the male hormone. But prior to that, on the subject that you have just mentioned, where you gave an opinion as to the male climeractic, do you know, as a result of your study, research, conferences, discussions and education, whether your opinion is shared by informed medical opinion?

A. I think that my opinion is shared by many people in [276] this respect, some of whom I would call highly informed.

(Testimony of Charles Huggins, M.D.)

Q. Again relating to the beneficial and toxic effects of the male hormone, in view of the fact that there are such toxic effects, what precautions, if any, are necessary in the use of testosterone?

A. I think that testosterone must always be administered under the supervision of somebody with some knowledge of these matters.

Q. What type of supervision would this be? What must the supervising person do before using the testosterone?

A. Well, the judgment of who shall receive testosterone and who shall not receive it is of very great importance. For example, if some of this material would fall into the hands of a ten or fifteen year old boy, it could do very great damage to him.

Q. What is your reason for saying that?

A. It can so damage the testes that the damage will be irreversible.

Q. The damage in what respect?

A. It can damage the production of the male germinal cells so that a young person or animal will not be able to produce spermatozoa. There will be a long lasting atrophy of the testes.

Q. In a male human of 15 you mentioned——

A. Or 10 or 5. I am talking now about a young person. [277]

Q. —would this have any effect on the normalcy of his sexual urge?

A. It would induce puberty, that is, the development of secondary sex characteristics, prior to the normal time. Whether it is desirable to induce

(Testimony of Charles Huggins, M.D.)

puberty at the age of 5 or 8 is a debatable thing. The fact is that most fathers do not advise giving children methyl testosterone to induce puberty at an abnormally early age. [278]

* * *

Q. Doctor, aside from the aspects of the young male, assuming now an adult using testosterone, what would be the nature of a precautionary step before taking testosterone?

A. Well, an adult who wished, naturally, to continue life with the production of children would have to be warned that with 10-milligram doses of testosterone very likely sterility would result, and with 25 milligrams certainly sterility would result.

The Court: Permanently?

A. No, sir. If he were taking the drug, then it would be permanent. If he were to discontinue the drug, the sterility would last anywhere from six months to some years. I am always alarmed to see young men or men who intend to have a family taking testosterone because it is a very dangerous agent and it will produce sterility in them.

Q. (By Mr. Danielson): Doctor, aside from the aspect of sterility, is there a toxic or harmful effect of testosterone in an adult, in which the aspects of sterility are the most serious?

A. There is a more subtle effect in a normal adult. [279] In a normal adult it will depress the activity of the pituitary gland so, on discontinuing the drug, it will be some months, weeks or months, before the pituitary has sufficiently recovered.

(Testimony of Charles Huggins, M.D.)

Q. I believe you have mentioned that you have had experience with the action or connection between testosterone and prostatic cancer?

A. I have.

Q. Doctor, on the basis of your knowledge of this subject, do you have an opinion as to the incidence of prostatic cancer in men of the age of 50?

A. This subject has been studied very much indeed in the last sixteen years. We know now that cancer of the prostate is the cause of death of 5 per cent of men over 50. It is one of the common tumors that one sees in a clinic, one of the common cancers. We know, further, that the disease is present in a very much larger percentage of patients, in anywhere from 14 per cent to 33 per cent of patients. Coming to autopsy, in males over 50 years of age, small cancers of the prostate are demonstrable.

Q. If you have an opinion, will you state the mortality rate from prostatic cancer in those who have a clinical prostatic cancer, which is diagnosable?

A. Until we did our work, the mortality was 100 per cent from the disease. Now, since we have learned that [280] androgen was a damaging agent to patients with cancer of the prostate and have discovered means of controlling the effect of androgens, the mortality rate has been reduced to 80 per cent. I mean 80 per cent died and 20 per cent apparently have extremely long remissions of the disease.

Q. Do you have any opinion as to what is this

(Testimony of Charles Huggins, M.D.)

mortality rate in the event testosterone is administered?

A. Well, testosterone makes the disease grow at a very rapid rate.

Q. Would that tend to increase or decrease the mortality rate?

A. A patient with cancer of the prostate, taking testosterone, would have a hundred per cent more mortality from that disease. [281]

* * *

Q. (By Mr. Danielson): Doctor, you say you have used testosterone in your practice?

A. That is correct.

Q. What procedure do you follow in administering testosterone?

A. Well, feeling as I do, that we are dealing with something that is not innocuous, but a powerful agent both for good and for harm, we proceed something as follows:

We make sure that the patient realizes that while taking adequate doses of testosterone, he will be unable to fertilize, and warn him accordingly.

Secondly, we try to make sure that the patient does not have a cancer of the prostatic gland. That can be done in two ways, the first way being examination of the prostatic gland through the rectum, by means of the finger palpation of the prostatic gland, and the second is by means of certain blood tests which have been established.

Mr. Elson: I did not hear the last sentence.

(Testimony of Charles Huggins, M.D.)

The Witness: Secondly, because of certain blood tests which have been established to indicate the presence of cancer of the prostatic gland.

Q. (By Mr. Danielson): Doctor, is there any supervision maintained during the continued treatment with testosterone?

A. Certainly. We see the patient at rather close intervals, to make sure that nothing untoward is happening. [282]

Q. Now, that is your opinion of a correct manner of administering testosterone?

A. Well, that is the method that we teach these young physicians.

Q. And do you have an opinion as to whether that opinion is likewise shared by informed medical authorities?

A. I think that it is.

Q. Now, to go back one moment, Doctor, you mentioned that the mortality rate in men over 50 years of age, from prostatic cancer, is about 5 per cent of all deaths, and that there is an incidence of prostatic cancer in men over 50 of about 14, 15, 16 per cent. Now, are there any men with prostatic cancers—do you have an opinion as to whether there are men with prostatic cancer who do not die from it and to whom it is not diagnosed?

A. We do, anywhere from 14 to 33 per cent of men over 50 actually have tiny Lilliputian cancers in the prostatic gland which are for the moment inactive and frequently in untreated old men these things remain dormant, never becoming causes of morbidity or mortality. The reason I think that they

(Testimony of Charles Huggins, M.D.)

sleep, lying dormant, is that fortunately in middle aged and older aged people, the male sex hormone level is not at the high level that it is in young adults and we think that nature has provided us with a slowdown mechanism of hormone production, and that these tiny cancers do not become [283] stimulated.

However, they can become stimulated when we increase the hormone content of the body artificially to that of a young man.

Q. What is the result when these little Lilliputian dormant cancers are stimulated? What is the result of that stimulation?

A. Then, the stimulation—it is easy enough to stimulate them, namely, to administer androgen, then they become full grown, flourishing things which spread throughout the body, producing prostatic tissue in bones, in liver, in lungs, in places where it does not belong and these kill the patient.

Q. Now, Doctor, is the use of methyl testosterone in a dosage of 25 milligram tablets, taken daily, adequate to provide this stimulus?

A. Whether it will stimulate all of them, I do not know. I know that 25 milligrams of methyl testosterone daily for some months will stimulate some of them.

Q. And your opinion, is that opinion likewise true in the case of linguets of methyl testosterone, 5 milligrams taken three or four per day?

A. It is true of methyl testosterone taken in 20 milligram doses per day.

(Testimony of Charles Huggins, M.D.)

Q. And would that likewise be true of 10 [284] milligram tablets of methyl testosterone taken three times daily or one time daily for an indefinite duration?

A. Well, with methyl testosterone, 10 milligrams taken three times daily, it would be a very great hazard. With 10 milligrams taken once daily, there would be some hazard, but not nearly as great as with the larger doses.

Q. You have mentioned that you have diagnosed and treated cancer of the prostate and have observed the effect of testosterone on the cancer of the prostate. Can you tell us in general what is the effect of testosterone on cancer of the prostate?

A. Well, it is something that has interested us very much. We found that testosterone made prostatic cancer flourish and that, conversely, removing testosterone made prostatic cancer wither and shrink and disappear.

And the reason it interested us so much was created a little interest in a few places in this country was that removing testosterone from patients with cancer of the prostate, human cancer shriveled up and disappeared, and this was the first instance where it was possible by drugs to cause widespread cancer in human beings to dry up and disappear.

Q. In addition to the use of drugs, are there any methods of removing the testosterone from the body?

A. The best way of removing testosterone from

(Testimony of Charles Huggins, M.D.)

the body of patients with cancer of the prostate is to remove the [285] testes and this little operation which we devised has now been universally adopted. So that some tens of thousands of patients each year are subjected to the operation of castration, to relieve cancer of the prostate.

Q. You mentioned producing the same effect by drugs. Could you explain that, please?

A. Well, if you give the female sex hormone in appropriate dosages, that has the ability of neutralizing the effect of whatever male sex hormones the patient is producing, so it vitiates what testosterone the patient is producing.

Q. How do you know that the use of testosterone actually accelerates or affects the growth of cancer of the prostate rather than it being some other element that produces that effect?

A. Now, we enter the field of clinical investigation. Occasionally we are forced to do things to human beings, in a few cases, to make a few observations that are not strictly in the patient's best interests. We do nothing that will do permanent harm or at least we attempt to, in medical investigation, but we found that the removal of the gonads would cause, in a very spectacular way, widespread cancer of the prostate to shrivel up, to shrink and to disappear.

Then, we had to try the converse and we gave testosterone to patients with mild cancer of the prostate and when that was done, either 10 milligrams of methyl testosterone a day given [286]

(Testimony of Charles Huggins, M.D.)

by mouth or 5 to 10 milligrams to 25 milligrams of testosterone injected, then the patient became very ill, indeed, and had to take to his bed.

Q. And by illness you mean an effect on the prostatic cancer?

A. The cancer became very much more active and we were able to see that because of these blood tests which we had, which showed very well the activity of cancer of the prostate.

Q. Now, Doctor, this effect which you have just now described of methyl testosterone, does that apply likewise to early cancer?

A. It activates early cancer, and in those cases I have seen, it does.

Q. Now, you have mentioned blood tests, Doctor. Would you advise us a little more fully on that aspect?

A. Well, cancer of the prostate forms a product called acid phosphatase. A normal prostate forms acid phosphatase but, when a patient gets cancer of the prostate, under certain circumstances this enzyme acid phosphatase gets into the blood and reaches a very high level and one can measure the acid phosphatase in a patient and make a diagnosis of cancer of the prostate, because when the acid phosphatase in the blood is at a certain level it clearly indicates the presence of cancer of the prostate, and so that this is a rather unique situation. By means of an enzyme in the blood, you [287] can diagnose the presence of cancer and if the

(Testimony of Charles Huggins, M.D.)

enzyme rises, due to some treatment, you know that the cancer is worse.

If the enzyme decreases as a result of another treatment, the cancer is better.

Q. What treatment would produce this decrease in the enzyme?

A. Removal of the testosterone by castration will cause a decrease of acid phosphates and the administration of female sex hormones will cause a fall, an amelioration of the cancer.

Q. And the reason for this latter, the female hormone, the reason it causes a decrease is what?

A. Because it overbalances the normal production of the male sex hormone that the testes is producing.

Q. And tends to be an antidote for the effect of the testosterone, is that correct?

A. Very well stated.

Q. Do you know whether there is any relationship between the presence or absence of testosterone and the presence or absence of the phosphatase in the blood?

A. Yes. When the testosterone is removed, then the phosphatase in most cases of cancer of the prostate comes down to normal.

Q. And if it is again replaced?

A. If it is again replaced, yes. Clinical [288] investigation, because we don't do that any more. It is an anti-social thing to do, in our opinion. Then, the phosphatase goes up and the cancer is worse.

Mr. Danielson: No further questions.

(Testimony of Charles Huggins, M.D.)

The Court: Before cross examination, Doctor, for the benefit of my reasoning in this matter, I would like to follow up on a few matters:

Examination

By the Court:

Q. As I understand, the production of the male hormone is in the testes and the initial source comes from the pituitary gland.

A. Yes, sir.

Q. Now, you have told us about some of the ailments that the testes are inclined to, as to what other glands have a relation to it, the pituitary, for instance, is it subject to ailments and disease?

A. The pituitary, sir?

Q. Yes. A. It is.

Q. They affect the production?

A. They do, sir.

Q. What are some of those diseases?

A. Well, the hormones work together as a well balanced team, very much like a team in sports. If they take away one [289] member, all of the members of the team suffer therefrom. Certain children are born with absence of pituitary cells that can stimulate the testes, and they are the children that I mentioned before who had hypogonadism.

Q. Yes. A. That is one of the conditions.

Q. Now, do other glands enter into the performance? For instance, a diseased gall bladder of long standing, would that have any effect on them?

A. No, sir, not unless the patient were very ill.

Q. Well, that would reduce the general vitality?

(Testimony of Charles Huggins, M.D.)

A. Any condition of severe illness with reduction of general vitality reduces the formation of the male sex hormone.

Q. Now, you mentioned two methods of determining if there was a cancerous condition in the prostate, one digitary and the other by blood tests.

A. Yes, sir.

Q. Are there any other tests?

A. Well, these are the most practical methods available. At times one can do a surgical operation and take a biopsy, but that is not a practical test. And actually we have found enough this spring to develop a more highly refined blood test than this phosphatase, so many workers now can tell with a high degree of accuracy the presence of cancer [290] in general in the body. This is another method beyond phosphatase, determination by still a blood method.

Q. These blood tests, do they call for microscopic work?

A. No, sir. It is a chemical determination. It is somewhat analogous to a Wassermann test for syphilis.

Q. With reaction?

A. Yes. It is not strictly comparable, but it is done by chemists in the same way.

Q. Well, an ordinary practicing physician, would he be capable of doing it in his own office?

A. Well, I think not, not unless he were chemically minded, but the average good sized hospital where there is a chemist, they could determine it.

(Testimony of Charles Huggins, M.D.)

Q. From blood specimens? A. Yes, sir.

The Court: I think that is all. I thank you.

Cross-Examination

By Mr. Elson:

Q. Doctor, in discussing this subject, we have to start, in a sense, from what is alleged in the information or otherwise the complaint with which the defendants are charged.

Now, one of the things that is charged is that this product, testosterone, methyl testosterone, 25 milligrams, one tablet daily, is dangerous because it may result in the [291] acceleration of the growth of an incipient carcinoma of the prostate.

A. That is right.

Q. Now, that is the kind of a cancer of the prostate that we are talking about. In your field, that is your specialty, isn't it, urology?

A. That is right.

Q. Well, now, let us think about the average general practitioner to whom a person goes and we will say complains of these various symptoms that Mr. Danielson read to you this morning.

Now, that man is not a physician, is he? He is a general practitioner.

A. That is right, sir.

Q. Isn't it your opinion that if such an individual complained of those symptoms, that such average general practitioner would, in all probability, prescribe testosterone propionate or methyl testosterone in linguets for the individual for a pe-

(Testimony of Charles Huggins, M.D.)

riod of say four to six weeks, and see whether or not those symptoms were relieved without going through the rather elaborate tests that you have described here today?

Do you get my question?

A. All except the average physician. I don't know what an average physician is.

Q. Well, I don't know how I can say it any more clearly. [292]

I am talking about the average type of competent, general practitioner that we will find in the average community.

The Court: An all-around family doctor.

Mr. Elson: An all-around family doctor, yes.

A. Then, I think some of them would prescribe in that way and some would not. I think that very few of informed physicians would.

Q. (By Mr. Elson): And by informed, what do you mean?

A. People who try to keep up with the latest literature, the latest dissemination of knowledge about these things. We have all kinds of people in our field of medicine. Some we are not very proud of and some we are intensely proud of.

Q. I understand that.

A. Well, some people study and learn. I think that the average good physician would not prescribe these things helter-skelter.

Q. Do you mean by that, that you do not believe that even though a man came in and complained of

(Testimony of Charles Huggins, M.D.)

those symptoms, that a good family doctor (we are talking about an average one now)——

A. Yes.

Q. ——not an outstanding one, the average good family doctor, do you think that he would, before prescribing use of this product, first palpate the prostate and then have a blood [293] test such as you have described conducted, to make sure?

A. I think that most of the average physicians would recognize that as no indication for sex hormones.

Q. Well, I don't think that is quite the answer to my question.

A. Well, I beg your pardon. I think the average physician would palpate the prostate but would not do blood tests.

Q. Does the blood test embrace a biopsy?

A. No. It is just a little blood taken from the vein (the witness indicates his left arm) but, as I told his Honor, that can only be done in rather well established hospitals.

Q. So that in your opinion the average doctor of whom we are speaking, and let us put it that way so I won't have to repeat it every time, the average doctor of whom we are speaking, in your opinion, would palpate the prostate to see whether or not he could feel anything abnormal there?

A. I think the average doctor would.

Q. And then, if he found nothing, isn't it reasonable to suppose that he would then prescribe testos-

(Testimony of Charles Huggins, M.D.)

terone, methyl testosterone, let us confine ourselves to that, he might inject it, I don't know, say for a period of four to six weeks and see if the symptoms were relieved?

A. Some of them would, some of the average ones, but I have no way to tell statistically whether 53 per cent of [294] them would or not.

Q. I see. A. I think the average, that——

Q. Let us come back again——

Mr. Danielson: May he finish?

Mr. Elson: Did you finish?

The Witness: I was going to say, by the average man I do not mean any genius, but I consider the average practitioner of medicine a scholar, a student, somebody who tries to keep up with the latest things. I recognize as well as you do that he can read these things in certain text books, that there is a male climacteric, when he doesn't feel so well he ought to take methyl testosterone or testosterone in one way or another, that he might take that. But, for many years now in our medical school and in a number of others, we have taught that these symptoms are the symptoms of being run down, overworked, fatigue, that one can usually accomplish these things usually better by a vacation on the beach than by drugs.

Q. (By Mr. Elson): That is true, that is what you teach in the university. A. Yes, sir.

Q. But isn't it true that the fine technical knowledge that you people are teaching in the university as applied to the subject of urology is not something

(Testimony of Charles Huggins, M.D.)

that is known completely [295] by the average doctor that we are talking about?

A. All of the young medical graduates of the last 10 years have had it.

They get it as a matter of the formal medical course.

Q. Now, with our average doctor that we are speaking of, hasn't it been your experience that he is really quite a busy man?

A. That is right.

Q. Not so much as during the war, but still he is a very busy man? Isn't it true that with such an individual, when he gets through administering to his patients, that there is not very much time for him to sit down and read scientific articles on the mass of subjects that are published pertaining to the human body, that is, prostate, heart, brain, and so on, and so on and so on? A. Yes.

Q. Isn't that true? A. It is true.

Q. Now, isn't it also true that the general practitioner, therefore, to a very large extent, relies upon the information concerning different products that is given to him by the manufacturer of them, in this case such as Schering, Roche-Organon and Ciba, isn't that true?

A. I don't think he relies on it quite as much as might be inferred. The average physician I think while he doesn't [296] have much time to read, has some time to read. I would deny that he had no time to read. I think the average physician reads the prescribed reading, namely, the Journal of the

(Testimony of Charles Huggins, M.D.)

American Medical Association, which practically every physician in the United States gets. This Journal has review articles time and again, ad nauseam, so if he misses it this month, he is apt to get it four months later, and I think the average physician learns in both ways. He learns from every person, doctor, nurse, orderly, medical student, from professors, drug salesmen and patients, in every other way, and also he does some reading. So just where he might get his information I would not be prepared to say. [297]

Q. Now, then, coming back to this incipient carcinoma, we have our average doctor, we will say, who examines a man and finds nothing out of order. "Incipient" in Taber's Medical Dictionary is defined as "beginning." Is it your opinion that, by such method of examination, the doctor we are speaking of would be able to find an incipient carcinoma of the prostate?

A. He can find some of them but not all.

Q. Would you say in the majority of instances he could find them?

A. I think in the minority of instances he can find them.

Q. In other words, isn't this true, that cancer starts from a cell and it multiplies and it has a wild growth throughout the body, which to the present time is uncontrolled, and so, until that cell is multiplied, or has multiplied, many thousands of times, there wouldn't be any physical abnormality of that

(Testimony of Charles Huggins, M.D.)

organ which could be detected by the doctor by that examination, that is, preliminary to stimulation, if it were stimulated by the agents which we know cause it to grow?

A. With androgen, then, in a few weeks, it could very likely be detected.

Q. I understand it is your opinion that, even if there were just one cell there, in your opinion, such a product as this would stimulate it more and more and more? [298]

A. That is my opinion.

Q. But I am talking about whether in its incipient stage the doctor would be able to find something there which would indicate to him a cancer of the prostate.

A. I think that the average physician might be able to recognize a minority of them. He certainly couldn't recognize them if there were one cell or a hundred cells or a thousand cells or a hundred thousand cells. But that is biologically very few because you can develop a hundred thousand cells in a week or two. But with a larger number you could pick them up so you will get a minority of cases. And the better the physician the more he will pick it up.

Q. You have conducted considerable experiments on this subject of the effect of testosterone on the growth of carcinoma of the prostate and you have written several articles on it?

A. Yes.

(Testimony of Charles Huggins, M.D.)

Q. Your first paper on that was about 1939, wasn't it?

A. I think I mentioned it in 1939 but the first formal presentation was 1941.

Q. At that time you were of the opinion that testosterone accelerated the growth of a prostatic cancer and you had no clinical proof of it, is that correct?

A. No, sir; that is not right. Whenever we made that statement, we had proof. I think I have had proof for [299] every statement I have made in medical literature.

Q. I don't have the article right here in front of me but I am referring to reports that others have made concerning reports that, in turn, you have made.

A. Yes, sir.

Q. And my remembrance of them was that in that report of yours of 1941 you were of the opinion and suggested that cancer of the prostate was accelerated by testosterone. [300]

None of those articles made the statement that you reported that you had clinical evidence that it was a fact other than a matter of your opinion based upon inferences from other things you had discovered?

A. No, sir; that is incorrect.

Q. It is?

A. Yes, sir. It states categorically, in black and white, in 1941, in our first publication, that we had proof of it.

Q. Will you tell me what actual proof you had

(Testimony of Charles Huggins, M.D.)

from clinical examination that testosterone accelerated the growth?

A. We could follow it by examining the blood, phosphatase enzymes in the blood.

The Court: Will you say that over, Doctor?

A. Yes, sir; phosphatase enzymes in the blood. Here for the first time man was capable of measuring the activity of a cancer by chemical means, which I didn't do. My assistant did it or I would do it and she would get the blood. So the examination was independent of knowing what treatment the patient was getting, how he was feeling, what size the cancer was, and all that. And we had this elegant method—and I hope you will excuse me for saying “elegant”—we had this elegant method, and we could tell the activity of the disease from day to day just as you could tell the activity of an infection by taking a patient's temperature two or three [301] times a day. We could tell whether the cancer was worse or not. And we gave testosterone and the cancer was worse in two or three days. And we would do other things. We would remove the testosterone and the cancer would be better. And that is all in *Cancer Research* for March, 1941.

Q. Did that appear in the form of a book?

A. Well, it was an article, so to speak.

Q. Where was the article?

A. *Cancer Research*, Volume 1, Page 293, March, 1941.

(Testimony of Charles Huggins, M.D.)

Q. Cancer Research, Volume 1, Page 293, 1941? A. Yes, sir.

Q. Now, can you state as a fact, Doctor, that the activity of that cancer was not actually caused by something else in the body and then stimulated by testosterone, that is, the effect of putting testosterone into the body, whether its effect upon something else, in turn, affected that and so on? In other words, was it a pathological or physiological condition that caused that acceleration and growth?

A. We were able to convince ourselves that it was the testosterone that did it.

Q. Have you had any more recent tests in which you feel that your conclusion or opinion is fortified? A. Certainly.

Q. And when was the most recent one?

A. I think June, 1949, in Cancer Research, Volume 9, [302] for June, 1949.

Q. With regard to those symptoms that Mr. Danielson read off to you, I believe I understood you correctly to say that, in your opinion, those symptoms or conditions would not be aided by testosterone even though they were the result of a hormone deficiency.

A. I think I must have been very unclear on the matter. Muscular strength and the development of the secondary sex characteristics in young castrates or patients with hypogonadism are helped very much by testosterone.

Q. How about these others, though?

A. Listlessness, lack of memory and those things cannot be helped in any person.

(Testimony of Charles Huggins, M.D.)

Q. Even if they were suffering from a hormone deficiency? A. Quite right.

Q. Did I understand you to say that you did not believe that there was such a thing as the male climacteric?

A. I did, although I qualified it by saying there is a difference of opinion in medical circles. I am certain on the point. There is no doubt in my mind that there is no male climacteric but I can quote some references by people who say that there is.

Q. I notice in the literature that there are a great number of articles in which the male climacteric is discussed. A. That is right. [303]

Q. And I take it you do not share the opinion of those investigators that there is a male menopause or climacteric and so on?

A. That is true.

Q. By the way, isn't it a fact that there is no appreciable hormone storage in the body?

A. Hormone storage is a matter of four or five days only.

Q. Does it last that long?

A. Yes; it lasts four or five days. I agree with you that indicates there is no appreciable hormone storage.

Q. In other words, four or five days you would not consider to be a period that would be long enough to be placed in the category of the secretion being stored?

A. No; that is not appreciable.

(Testimony of Charles Huggins, M.D.)

Q. You spoke of the patients in your hospital. I was just wondering when you were testifying who comes to your hospital. Is it just anybody that wants to come in? A. Yes, unfortunately.

Q. And I suppose that they are people who don't have the funds to go to a regular hospital and pay for it?

A. No, sir; that isn't quite right. The University of Chicago Hospital is owned and operated by the University of Chicago. In order to keep the roof over the heads of the professors, it is necessary for us to charge a fee. So that the [304] patients that we see are private patients in large part and we see charity patients also. But most of them pay for their service.

Q. Is it your opinion that testosterone causes cancer of the prostate?

A. It is not known what causes cancer of the prostate. It is my opinion that it does but that is a qualified opinion. We have no definite knowledge. All I know is that testosterone activates it.

Q. It couldn't very well cause cancer of the prostate, could it, because, if it did, why every normal male would be doomed to die of cancer of the prostate?

A. No; that is not very acceptable reasoning to me. It is my impression that testosterone causes it but we have very salutary mechanisms in the body whereby only one-third of us get it, and we have it 14 to 33 per cent at the age of 50 probably. There are salutary mechanisms whereby the hor-

(Testimony of Charles Huggins, M.D.)

none level falls 50 per cent and the tumor is not stimulated, but it can be stimulated when we give testosterone.

Q. Your opinion would be, then, that in an individual whose testosterone production did not decrease with advancing years, the testosterone that he produced would cause cancer of the prostate?

A. I think so, but that is just an opinion.

Q. You have no particular evidence to support it? [305] A. No.

Q. By the way, that opinion of yours is not shared by others, is it?

A. Well, I don't know about that.

Q. Pardon me just a moment. Doctor, I have here a September 28, 1946, issue of the Journal of the American Medical Association, and, under "Queries and Medical Notes," on page 252, this question was submitted by a doctor in New Jersey to the American Medical Association for answer. The question was: "A man aged 46 with impotentia coeundi has been administering 25 milligrams of methyltestosterone to himself every other day for the past year with gratifying results. The patient now insists on having a pellet of testosterone propionate inserted in his thigh. Can the administration of 25 milligrams of methyltestosterone every other day be continued indefinitely or could the pellet be inserted without danger of eventually causing cancer of the prostate?"

"Answer. Testosterone propionate is probably more effective when administered by injection than

(Testimony of Charles Huggins, M.D.)

when implanted in the form of pellets. There would be no objection to a trial of the material in pellets. The danger of the development of carcinoma of the prostate is no greater with one form of administration than with another.

“Carcinoma of the prostate apparently occurs rarely in a patient who is receiving treatment with testosterone propionate; [306] the medicament may be given when indicated without worrying about its carcinogenic properties. Every patient receiving it should be carefully examined to make sure that carcinoma of the prostate is not present before treatment is started. Under such circumstances the treatment, of course, would not be given. If carcinoma is not present initially, the likelihood of inducing it with testosterone propionate is evidently so slight that it may be disregarded.”

Do you share the same opinion as the writer of this answer? Would you like to see this?

A. Yes. Could I look at it?

Q. Yes.

A. As I stated before, we don't know what the cause of cancer of the prostate is. I agree that every patient receiving it should be carefully examined to make sure that cancer of the prostate is not present before treatment is started. The editor says, “If carcinoma is not present initially, the likelihood of inducing it with testosterone propionate is evidently so slight that it may be disregarded.”

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I would disagree with that although, as I say, I don't know what the cause of this is.

Q. By the way, would you think that, if a person were administered an injection of 50 milligrams of testosterone propionate, and then were given 10 milligrams of methyltestosterone, a hundred tablets, to be taken once a day, that [307] there might be—or, in your opinion, would that tend to accelerate the growth of an incipient carcinoma?

A. Yes, sir.

Q. At one time it was your opinion that the method of combating cancer of the prostate was by castration?

A. It still is my opinion.

Q. But I think that in your direct examination you stated that you didn't do that now as frequently as formerly?

A. Oh, no. That is the best method of control and we still do that.

Q. Oh, I beg your pardon. I had understood that you had said that you did do it and now you don't do it.

A. No. We have these two methods. The castration operation is more effective than the female sex hormones.

Q. I think you briefly said that—wait a minute. You know Dr. Ira T. Nathanson don't you?

A. Very well.

Q. Are you familiar with his article appearing in the symposium entitled "Recent Progress in Hormone Research, Volume 1, 1947"?

A. No, sir.

(Testimony of Charles Huggins, M.D.)

Q. In that article, entitled "Endocrine Aspects of Human Cancer," he discusses tumor of the breast, cancer of the breast and cancer of the prostate gland and, finally, in conclusion, it is stated as follows: "A considerable number [308] of data bearing on the relation of the endocrine organs to tumors have accumulated. The administration of sex hormones through experimental animals has resulted in the production, the augmentation and the inhibition of benign and malignant tumors. These changes are limited to definite types of tumors in different species, as well as to certain strains in any one species of animal. Thus, there are other factors that determine the reaction of a tissue to a hormonal stimulus, and the susceptibility of an animal to the induction of neoplasm. It is difficult to interpret these facts in terms of human cancer. Nevertheless, they are of extreme importance in the study of the origin and course of cancer in general." Would you share the conclusions stated there by Dr. Nathanson with respect to the causing and acceleration of the growth of a prostatic cancer?

A. I didn't think that he mentioned anything about that.

Q. He was speaking of the cancers he had discussed in his article, one of which was cancer of the prostate.

A. I think animal research has a greater significance toward human problems than he states.

Q. Animal experiments don't mean necessarily

(Testimony of Charles Huggins, M.D.)

you can translate those into the same effect on humans, does it?

A. There are some reservations but, in general, you can.

Q. In experiments with rats, for instance, is it usual to select rats or mice for experimental purposes who are [309] particularly susceptible to cancer? A. Correct.

Q. Is it your opinion, though, that animal experimentation or using animals as subjects can accurately be translated, in so far as cancer of the prostate is concerned, to its effect upon humans?

A. Well, the type of cancer of the prostate that humans have has never been produced in animals.

Q. I wonder if this article here would have any significance to you in connection with what you have just said. It is in the book entitled, "Endocrinology of Neoplastic Diseases." Are you familiar with it?

A. I am familiar with it. What is the date of it?

Q. 1947. On Page 207 the author of the article says, "In spite of the evidence in man that carcinoma of the prostate is improved by orchidec-tomy, and made worse by the injection of andro-gens, there are no reports of the production of car-cinoma of the prostate in animals by injection of androgens. These studies include those of Rossole and Zahler on adults and of Zahler on senile dogs. In both instances the period of study was relative short and the amount of androgen given was prob-

(Testimony of Charles Huggins, M.D.)

ably inadequate. Zuckerman and Parkes injected 242.5 milligrams of testosterone propionate into a castrated rhesus monkey during 91 days. The histologic structure of the prostate was normal.” [310]

If my mathematics are correct, that would figure out about 2.66 milligrams injected every day. Would that have any significance in connection with what you have told us about the effects of testosterone propionate or testosterone accelerating the growth of cancer?

A. No, sir. The fact that it has never been produced in experimental animals, while distressing to a professional investigator like myself, doesn’t mean that the thing is hopeless. What we know about cancer of the prostate is as follows: It has never been observed in a castrate man, if a person was castrated in early life for one reason or another. So I know this, that the presence of the functioning testes is essential. It must be there for some years; otherwise no cancer. [311]

* * *

Q. Doctor, eliminating eunuchoids and castrates from consideration, approximately how much testosterone in one form or another do you think that your hospital has prescribed say in the last five years?

A. Well, the only indication we have accepted for those is in the cancer of the breast, in women, where the drug has a different effect than it has

(Testimony of Charles Huggins, M.D.)

in the male. There it causes the cancer to decrease.

Q. Pardon me. I am eliminating women. I am speaking only about men.

A. I don't think we have prescribed any in our hospital.

Q. In the last five years? A. Yes.

Q. Now, on this subject of the male climacteric, you are familiar, of course, with the publication, *The Urologic and Cutaneous Review*?

A. Yes, sir. [313]

Q. And with Hans Lisser and Robert F. Escamilla? A. Yes, sir.

Q. And they have written for that, as you recall, on some occasions? A. Yes.

Q. Now, I call your attention to volume 46, page 87, of the issue of February, 1942, an article appearing by them, entitled "Testosterone Compounds in the Male. Clinical Indications and Methods of Administration." On page 90 they state as follows, under the subheading "Male Menopause":

"Until recently the male menopause has been ignored except for rather bizarre attempts at rejuvenation by testicular graftings or by tying the spermatic cord (Steinach's operation). Perhaps this neglect was due to the conception that the male menopause consisted merely of the natural diminution and final loss of libido and potency in advancing years. Little heed was given to the less obvious but more important manifestations consisting of mild vasomotor flushes, increasing irritability,

(Testimony of Charles Huggins, M.D.)

failing memory and decreased capacity for mental effort. The customary day's work is not accomplished as speedily, as cheerfully or as effectively as before. We are inclined to believe that during this period conservative androgen therapy is indicated and may be highly beneficial. However, care must be exercised to avoid undue sexual stimulation, especially in men [314] between 50 and 70 years of age who suffer from hypertension or show evidence of arteriosclerosis or myocardial damage."

Are you in agreement or disagreement with the statement of the writers of that article?

A. I am in disagreement with the indications for the drug.

Q. Now, in the same publication, a different volume, volume 50, issue of March, 1946, there is an article entitled "A Contribution to the Endocrine Aspect of the Impotence Problem—A Report of Thirty-nine Cases," by Harry Benjamin, M. D., of New York City. Do you know Dr. Benjamin?

A. I know the name.

Q. In that article he discusses those cases and states as follows, on page 143:

"As for gratifying general results, they were observed in 72% of the cases in the group receiving parenteral treatment, and in 71.4% of the patients who were given methyl testosterone. These figures are in close agreement and indicate that there is no difference in the general response irrespective of the compound administered. Improvement of appetite, gain in weight and physical strength, ameli-

(Testimony of Charles Huggins, M.D.)

oration of urinary disturbances and increased memory, endurance, ability to concentrate, etc., were frequently observed in both groups.”

Are you in agreement or disagreement with the statements [315] that I have read of the author?

A. In disagreement, sir.

The Court: What was the date of that last?

Mr. Elson: 1946, your Honor, March, 1946.

Q. Now, in the Journal of Urology, volume 49, at page 872 of the issue of June, 1943, is an article entitled “The Male Climacteric: Additional Observations of Thirty-seven Patients, by August A. Werner.”

Do you know Dr. Werner?

A. I know the name.

Q. Now, if you will bear with me, if your Honor please, this will be a little bit longer than the others. On page 872 the author speaks, under the subheading of “Subjective Symptoms,” he says:

“Since the climacteric is the result of a neuro-endocrine imbalance, it is necessarily functional. The subjective symptoms accompanying gonadal hypo-function render the patient more uncomfortable than do the objective signs. As reported for the female, the symptoms in the male may be classified as (1) nervous, (2) circulatory and (3) general.”

Then, dropping down, the writer makes this discussion under those three symptoms that I have just read:

“Nervous symptoms. All patients complained of

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an intense subjective nervousness, or a feeling of tension. There is a sensation of an inward tremulousness, which usually does [315] not become manifest. This is especially noticeable upon arising during the night or in the morning. Excitement or fatigue accentuate it, and then a tremor may be noticeable, which should not be attributed to hyperthyroidism.

“Nervous people are irritable and they are easily aggravated or excited to anger by word or deed. Noises of playing children, the radio, almost anything stirs them to action. In fact, they need no special stimulus. They are hard to please and frequently the family or associates say that they can hardly get along with them. In many instances they acknowledge this condition, but state that they cannot help being so.

“Excitability is a nervous state in which the persons respond to ordinary stimuli in an exaggerated manner, especially as regards the psychic response. Unfavorable news, slight mishaps, arguments, all manner of little occurrences that would not disturb a normal individual cause quite a nervous and mental flurry.

“A large majority of these patients complain of sleeping poorly. They may be restless, sleeping only for short intervals during the night. Some fall asleep quickly upon retiring only to awaken within one-half hour and remain awake for varying lengths of time. Others do not sleep upon retiring until after midnight. Some complain that

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they sleep well until 2 or 3 a.m. and then remain awake until morning. [317] Patients who do not sleep at night find themselves exhausted the next day and must sleep during the day time. This desire to sleep during the daylight hours must not be confused with somnolence.

“Formication, a sensation as if ants or insects were crawling over the skin, especially on the back and body, is frequently complained of. There may be itching, prickling or tingling of the skin. Numbness and tingling of the hands, feet, or one or more of the extremities often occurs. Frequently these people awaken while lying in bed and find the extremities completely numb. Some have stated that they had to sit up and rub their arms or legs, and one person awakened and arose to go to the bathroom and fell to the floor because the feet were numb.

“Headaches of various types and location occur, but are rarely migrainous. They may be described as a dull to severe ache, usually not neuralgic, and may occur irregularly or be continuous. Their location may be temporal, frontal, vertex or occipital, with any combination of these. There are two types of headaches which have almost specific diagnostic importance in gonadal hypofunction: viz., vertex and occipito-cervical. The occipito-cervical ache may radiate to the neck, over the scapular regions or down the spine. It may last from hours to several days and when present the patients complain that their mind seems hazy or fogged, and this

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mental [318] haziness may last for days. The vertex ache is frequently described, as if a great weight were resting on the head, or as a feeling of pressure.

“There is decreased memory and ability for mental concentration. Cerebration is slowed, and they are forgetful, especially for recent events. If they read an article they cannot tell what they have read, and must reread it several times before it registers; names, figures and dates are especially difficult to remember.

“Depression or mild melancholia is an important symptom; when this is present the patients have loss of interest in their work, their home, or in their past pleasurable diversions, they want to avoid people and may cry for no special reason. They realize that there is something wrong within themselves and they become introverts and are ill at ease, have fear of some impending danger and worry unnecessarily. There is a loss of self-confidence and a feeling of futility. At this stage of the condition, these patients verge on psychosis, may be self-accusatory, have thoughts of self-destruction and may actually commit the act. This extreme stage has previously be referred to as involutional melancholia; it is a psychosis, but of definite endocrine origin, as described above.

“Circulatory symptoms. Hot flushes are characterized by a sudden redness of the face and neck, upper chest and at [319] times most of the body. This is akin to blushing and is due to dilatation of

(Testimony of Charles Huggins, M. D.)

the superficial capillaries of the skin. It is a very uncomfortable sensation, generally of short duration but may last $\frac{1}{2}$ hour or even longer, if the statements of some patients are correct. Frequently this is described as a smothering sensation. They may be accompanied by profuse perspiration. There may be vertigo and scotomata or tingling or prickling sensations over the head, neck and body. Occasionally, hot flushes alternate with chilly sensations over the same area or follow them. Hot flushes may accompany disturbances of the cardiovascular system, especially arteriosclerosis with hypertension, but these conditions can be eliminated by proper diagnosis.

“Tachycardia, palpitation and dyspnea, more than usual upon moderate effort, without evident cardio-renal disease is complained of. Walking a short distance, ascending a flight of stairs, almost any moderate effort causes cardiac consciousness. Many of these patients have this group of symptoms occur while sitting quietly or even while lying in bed. At times they are awakened from their sleep by tachycardia and palpitation.

“Vertigo, especially with change of position is often noticed, with no cardiovascular lesion to account for it. Vertigo, tinnitus and scotomata are usually associated symptoms; of these vertigo occurs most frequently. Scotomata may [320] occur as dark, red or silvery specks floating before the eyes.

(Testimony of Charles Huggins, M. D.)

“Cold hands and feet at any season, is complained of by many of these patients.

“The pulse is usually not affected much, unless there is some intercurrent condition and the blood pressure may be increased in an occasional patient.

“General symptoms. Lassitude and fatigability are often present. Some of these people state that there is marked decrease of endurance, they fatigue easily. Others complain that they are constantly tired, or that upon arising in the morning they are unrested or feel more tired than when they went to bed.

“Vague pains are complained of and their location may be as legion as the distribution of the nervous system. However, when a patient complains of pain, one must make a definite effort to determine its significance, before it is lightly dismissed.

“Potency is something apart from libido. Potency is more easily determinable in the male than in the female for obvious reasons. Libido in a large degree depends upon the mental reaction and may be present in the absence of potency. The author has had quite a few women state that libido was more marked during the menopause, then at any other time in their life. This can be easily explained in both sexes because libido operates through the conscious mind. [321]

“Constipation is frequently found in hypofunction of the thyroid and pituitary glands in which we have a relative vagotonia. Many of these patients complain of a gastric syndrome character-

(Testimony of Charles Huggins, M. D.)

ized by distension and eructation after meals with no organic lesions. This is probably secondary to the nervousness and the constipation and usually disappears with sedation and proper elimination. While some cases of constipation may have a glandular basis, the vast majority are probably due to improper habits, diet, gastro-intestinal disease, etc.”

Now, are you in agreement or disagreement with the author's discussion of the three symptoms and the sub-symptoms, or the three symptom headings that he classes as associated with that condition?

A. I think they are absurd. I am in complete disagreement.

Q. Now, Doctor, on the subject of fertility—

Mr. Danielson: Is there any explanation that you could make, Doctor, of these symptoms on this particular discourse on this article?

The Witness: If I could speak for about a minute. Due to our treatment, we have had a great opportunity to remove the testes of very many men with cancer of the prostate gland and so that we know from intimate experience what the symptoms of male hormone deficiencies are since removal of the [322] testes is the most drastic type of male hormone deficiency that it is possible to obtain; none of these patients complains of nervousness, tremulousness, irritability, constipation, insomnia, eructation, scotomata, vertigo, headaches, all these other things. These patients feel well except for one thing, they develop hot flushes and profuse perspiration attacks. These symptoms, it seems to me

(Testimony of Charles Huggins, M. D.)

that these writers have spoken about, we attribute them to fatigue and psychoneurosis and not due to hormonal deficiency because a man completely deprived of testes does not complain of any of these symptoms.

Q. (By Mr. Elson): Now, Doctor, however, the article of the Journal of Urology is considered to be an authentic publication, isn't it?

A. Well, the Journal is usually pretty good.

Q. And it is quite widely distributed to medical men who are interested in that phase of medicine?

A. That is quite right.

Q. Pardon me?

A. I still deny them as taking them as a sign of male hormone insufficiency.

Q. And it is to be found in practically every well-stocked medical library in the country, isn't it?

A. Quite right.

Q. Isn't Dr. Werner considered to be a urologist or a [323] doctor of considerable repute in that field?

A. Dr. Werner is an endocrinologist and he is well known. Let us put it that way.

Q. In other words, you disagree with his statements?

A. I think he is well but not favorably known.

Q. How about Dr. Lisser and Dr. Escamilla?

A. The same.

Q. Now, on this subject of fertility, I am going to do what I did yesterday with counsel's state-

(Testimony of Charles Huggins, M. D.)

ments, and cut our time short and accomplish the same result, anyway.

I have here a little pamphlet that is put out by the Professional Service Division of Ciba Pharmaceutical Company and in that the various statements are made which are reported to be from the literature. In discussing the effect of testosterone propionate and methyl testosterone on the testes, they say as follows, and I am only reading the last sentence, and that is on page 8 of that pamphlet, and the pamphlet number is 108:

“Other authors have pointed out that both number and viability of the spermatozoa can fluctuate during the continued use of androgens or that the cause is usually of minor significance as compared to the enormous improvement obtained in all other respects.”

The quote being an article by Dr. Lisser and Dr. Escamilla appearing in the *Urology*— [324]

A. *Urology and Cutaneous Review*.

Q. —*Urology and Cutaneous Review*, volume 46, page 87, written in 1942.

Are you in agreement or disagreement with the statement that is quoted of the authors there?

A. If I understand it correctly, my position, I would like to say that—let us begin again. So far as the doses of androgen will cut down the sperm count—the statement that you read to me was rather ambiguous that there were fluctuations in certain patients, but despite those fluctuations, better go ahead with the treatment anyway because of good

(Testimony of Charles Huggins, M. D.)

improvement in the sense of Dr. Lisser and his colleague. But actually the sperm count, provided enough testosterone is taken, goes right down and may reach zero. [325]

Q. But you are not, as I understand it, then, in agreement with their opinion that that fact is of minor significance as compared to the enormous improvement obtained in all other respects?

A. No, sir; I am not because it may be of very great significance if a husband becomes sterile.

Q. Isn't it a fact that the age bracket of most men who take testosterone is generally 45 on up?

A. I know a lot of young people who would take it if they could get hold of it.

Q. I am not going to object to that. It is, obviously, a conclusion. Do you feel there are a lot of young people who would take it if they could?

A. Yes.

Q. Getting back to my question, isn't it true that the majority of people who take testosterone are in the bracket of 45 and up? A. Right.

Q. Now, is it your opinion that men within that age bracket are generally interested in producing offspring?

A. Generally, they are not.

Q. Just one other question. You are aware, aren't you, that hundreds of thousands of packages of testosterone in one form or another are sold by Schering Corporation, the Ciba and Roche-Organon every year; that it may run into the [326] millions? I don't know. A. That is right.

(Testimony of Charles Huggins, M. D.)

Q. Isn't it strange to you, Doctor, that, if what you say is true, that so many men have a dormant prostate cancer and that testosterone will accelerate its growth, the incidence of actually diagnosable prostatic cancer and recognizable distress of the individual because of it, in view of that large quantity sold, it is not greater than it is?

A. I think that 5 per cent of men over 50 dying with cancer of the prostate is a very high percentage as it is.

Q. Then, you attribute that, do you, or would you in part, to the large volume that is sold by these companies?

A. I didn't say that. I think that this is a very common disease. I am impressed by the large amount of it in the American population.

Q. Isn't it your experience that for the most part testosterone throughout the United States is sold on prescription? A. Right.

Q. So that, if testosterone is responsible for a high percentage, as you say, of men dying of cancer of the prostate, then the fault lies with the doctors who administer it?

A. I think that the drug is a very valuable drug, and we must always prescribe testosterone. The only point I have is it must be given under supervision to detect the serious [327] things that happen.

Q. Wait just a moment. I think I am about through. I have no further questions.

(Testimony of Charles Huggins, M. D.)

Redirect Examination

By Mr. Danielson:

Q. I have just a few questions for clarification, your Honor. Doctor, what do you mean by orchidectomy?

A. That is surgical removal of the testes.

Q. And what do you mean by the expression "indications for the drug"?

A. Indications for the drug in the male—the only ones I recognize are hypogonadism and castration, for other reasons than for cancer of the prostate.

Q. Doctor, when an early or incipient cancer of the prostate is diagnosable, is it possible, through male hormone therapy, by periodic regular examination of the prostate, to diagnose a carcinoma of the prostate while it is still small?

A. It is.

Q. And while it is still susceptible to rather favorable treatment, is that correct?

A. It is.

Q. Doctor, another point, regardless of what an average doctor might do on examining a patient prior to using hormones, or regardless of whether he actually detects an early or incipient carcinoma of the prostate, isn't it a fact that the methyl testosterone would still accelerate such a growth?

A. Certainly. [328]

Q. And on another point, directing your attention to the so-called male climacteric, regardless of whether or not there is such a thing as male menopause or male climacteric, are the symptoms

(Testimony of Charles Huggins, M. D.)

which have been brought into evidence several times the symptoms of a male hormone deficiency?

A. The symptoms described by Dr. Lisser and by these other gentlemen that Mr. Elson read are not, in my opinion, due to a male hormone deficiency.

Q. And next to the last question, I understand the latter part of the testimony was that in the greater portion of the United States these drugs are sold under prescription.

This would indicate, would it not, that such drugs were administered by physicians and under their supervision?

A. That is correct. My point is that this is a very powerful drug and, if it is properly used, it is extremely significant to the community as an important drug.

Q. Under such medical supervision, an early prostate cancer could be detected, is that correct?

A. Yes; in addition to a very dangerous condition later.

Q. And, finally, again, Doctor, assuming a man who has no prostatic cancer or other pathological condition which would be an indication against the use of testosterone, would the use of testosterone produce within him any harmful effects of which he would be personally aware?

A. It might produce harmful effects of which he would [329] not be aware but of which he would be aware after some months or years.

Mr. Danielson: No further questions.

(Testimony of Charles Huggins, M. D.)

Recross-Examination

By Mr. Elson:

Q. Did I understand you to say, Doctor, that practically every state required testosterone to be sold on prescription?

A. I don't know the legal aspects of this, sir. It is my impression that most of the testosterone used in Illinois, for example, is under a physician's prescription.

Q. As a matter of fact, and, if it refreshes your recollection, all right, and, if it doesn't, all right, aren't there only three or four states in the United States that require it to be sold under prescription?

A. I never went into the legal aspects of it, sir.

* * *

The Court: Doctor, would you be able to give us an [330] estimate as to the male population of the country who, at some various times in their lives, are afflicted with flushes and sweating, this long list of symptoms given in this article by the Doctor? Would you be able to state whether there are such symptoms which are common to nearly all of the male population or whether they are sporadic?

A. I think the symptoms are very common, indeed, your Honor; I think very much more common than in people who work under tension, that is, than among people of low intelligence. I think that most intellectual workers complain of one or more of these symptoms sometime in their lives.

(Testimony of Charles Huggins, M. D.)

The Court: It has been mentioned a number of times here about incipient and dormant cancer in the prostate and that it comes from an accumulation of cancer cells, as I understand it. Are cancer cells inherent in the prostate gland?

A. By that do you mean does every man have to have them?

The Court: Are they just there waiting for something to accelerate their growth there?

A. I think that they are in somewhere between one-sixth and one-third of the male population over 50; in the other two-thirds or five-sixths that there are no cancer cells.

The Court: They just naturally are in a large proportion of the population?

A. Roughly, a third of us over 50.

The Court: Is that the favorite spot in the human [331] organism for them to reside?

A. No, sir. Cancer is commoner in both the skin and the stomach and in the human male the prostate is number three.

The Court: I want to ask you another question that might be helpful to me. I have heard it said many times that Vitamin E, which is, I believe, a preparation from wheat, has certain effects. What I wanted to ask you is is there any relationship or any effect of Vitamin E on this male hormone we have been talking about?

(Testimony of Charles Huggins, M. D.)

A. There is no relationship that has been recognized as yet, sir, to the best of my knowledge.

The Court: No relationship or no effect?

A. No, sir, they are two independent things. Vitamin E is essential for the development of sperm, but there is no close relationship and there has been no relationship detected between that and testosterone.

The Court: That is all.

Mr. Danielson: No further questions.

Mr. Elson: I have no further questions.

Mr. Danielson: Dr. Glass, please. [332]

SAMUEL J. GLASS, M.D.

called as a witness on behalf of the government,
being first duly sworn, testified as follows:

The Clerk: Your full name?

A. Samuel J. Glass.

The Clerk: G-l-a-s-s?

A. Right.

Direct Examination

By Mr. Danielson:

Q. What is your address, Doctor Glass?

A. My office address is 360 North Bedford Drive,
Beverly Hills.

Q. Of what school or schools are you a graduate
and with what degrees, please?

A. I have the M.D. degree from the Medical
Faculty of the University of Toronto.

(Testimony of Samuel J. Glass, M.D.)

Q. And in what year was that? A. 1923.

Q. What post-graduate training did you have?

A. Three years of hospital work, one year at the University of Toronto and two at the Hospital of the Good Samaritan in Los Angeles.

Q. Are you now engaged in the practice of medicine? A. I am.

Q. How long have you been so engaged?

A. Since 1925. [333]

Q. Do you specialize in any particular field of medicine?

A. I do. I practice a specialty known as endocrinology.

Q. And will you please explain generally what you mean by endocrinology?

A. It is a study and a treatment of diseases emanating out of disorder of the functions of the endocrine glands or those responsible for the internal secretions of the human body.

Q. Are you associated with any local hospitals or clinics?

A. I am with the Cedars of Lebanon Hospital.

Q. In what capacity?

A. I am the Director of the Department of Endocrinology, in which there are three distinct clinics, the general endocrine clinic, the thyroid clinic and the sterility clinic.

Q. Are you a member of any professional societies, Doctor?

A. I am a member of the local Los Angeles County, State and American Medical Associations;

(Testimony of Samuel J. Glass, M.D.)

I am also a member of the American Society for the Study of Sterility; the Association for the Study of Internal Secretions; the Society for Experimental Biology and Medicine; the Association for the—well, I have forgotten the name of the other one. It is too long-winded.

Q. What qualifications are required for membership in the Society for Experimental Biology and Medicine?

A. One must be a qualified investigator in either the [334] medical or the biological field.

Q. Does that include original research, Doctor?

A. Original research must have been done before election to membership.

Q. Have you published in any scientific publications the results of some of your investigations?

A. I have published many reports in many different journals.

Q. Are you familiar with the female sex hormones, Doctor?

A. I am.

Q. In your practice, do you make use of the female sex hormones?

A. Extensively.

Q. Are they known also as estrogens, Doctor?

A. That is correct.

Q. About how many years have you utilized these substances?

A. Approximately twenty.

Q. Could you tell us briefly in what manners the estrogens can be administered?

A. They may be administered in a variety of routes of administration, orally, hypodermically, by

(Testimony of Samuel J. Glass, M.D.)

pellet, implantation under the skin, and by the inunction or massage into the skin of these various compounds. [335]

Q. What is meant by the term "mixed natural estrogens"?

A. They are natural derivatives or products from the extractions of pregnancy, urine from the mare, or the human, and, also, from the human placenta.

Q. Do they contain estrone, Doctor?

A. In large measure, among other estrogenic compounds.

Q. An estrone is, likewise, a female sex hormone, is it?

A. Right.

Q. Is mixed natural estrogen considered to be an effective estrogen?

A. Yes.

Q. Can it be administered in the same manner as these other estrogens?

A. Yes.

Q. That is, it can be rubbed onto the skin and absorbed?

A. Yes.

Q. Is this considered an effective route of administration?

A. It is not popularly or commonly used as a good method of administration.

Q. Can its efficiency be compared with oral or subcutaneous administration?

A. That varies with the medium in which the hormone is present, whether it be in an alcoholic tincture or whether it be an ointment base, and the character of the ointment [336] would change its absorption but approximately 20 per cent can be

(Testimony of Samuel J. Glass, M.D.)

absorbed from an ointment base through the skin.

Q. Have you had personal experience in this route of administration? A. Yes.

Q. For what conditions have you administered estrogens through the skin, that is, by rubbing them into the skin?

A. There are two common conditions which have warranted the use in my experience, the use of topical application of estrogens in under development in the female breast and superfluous hair in females who manifest a tendency to a masculine beard, for example.

Q. Have you used the estrogenic material in this manner for the purpose of enlarging human female breasts? A. Yes.

Q. And, on the basis of your professional training, education, your study and your experience, do you have an opinion as to whether it is possible to enlarge the female human breast by applying estrogens directly to them?

A. I believe it is possible.

Q. Doctor, I show you a copy of Government's Exhibit No. 3, a label relating to Menformon Dosules, and ask you to read that label to yourself. Here is the original document, which you may read a little more easily.

A. Yes; it is a little faint. [337]

Mr. Danielson: May the record show this is Government's Exhibit No. 3?

Q. Assuming that the product referred to in

(Testimony of Samuel J. Glass, M.D.)

that label is the composition which is declared on that label, is it a mixed natural estrogen?

A. Yes.

Q. Are you familiar with this preparation?

A. Yes.

Q. Do you mean you have had personal experience with it? A. Yes.

Q. For what purpose did you use it, Doctor?

A. I tried it out in a number of patients for the specific purpose of enlarging the underdeveloped female breast.

Q. Your experience for this purpose would include about how many applications of this drug, in round numbers?

A. Oh, I remember this firm having sent me a couple of hundred of these dosules for clinical trial, a good many years ago; the exact time I don't remember. I used them all without result, without good results.

Q. On the basis of your training, education, and the sum of your knowledge of this subject, do you have an opinion, Doctor, as to the efficacy of a product such as Menformon Dosules described in Government's Exhibit No. 3, their efficacy in enlarging the breasts of women?

A. I found this particular product to be of no value [338] for that purpose.

Q. Doctor, now I refer your attention to Government's Exhibit 3-B, a circular which accompanied this product, and I call your attention to the last page thereof, where the following statement appears: "Breast Development. Direct Action on

(Testimony of Samuel J. Glass, M.D.)

the Mammary Gland. Estrogens can be absorbed through the skin of the human female directly into the breast tissue and by this route can produce characteristic stimulation or mammary growth, and the result is definite breast growth of considerable degree. Since underdeveloped breasts are often a considerable worry to women, cutaneous estrogen therapy of hyposmastia presents a valuable addition to the physician's therapeutic resources. 25 days supply, 50,000 International units, \$7.50; 25 days supply, 125,000 International units, \$14.00." Doctor, on the basis of your professional training and experience, your education and your studies and research, would that statement be true as applied to the product described in Government's Exhibit 3, the Menformon Dosules?

A. That dosage would be inadequate in my experience. [339]

Q. (By Mr. Danielson): Doctor, have you had experience with other estrogenic preparations of same or greater potency for this same purpose?

A. I have.

Q. For example?

A. Well, I have used products of similar composition, but with estrogens in the range of five to twenty times greater than these specified in the pamphlet and the label of the dosules.

Q. And likewise, for the purpose of enlargement of the breast? A. That is correct.

Q. And what were the results achieved with this preparation, the stronger preparation?

(Testimony of Samuel J. Glass, M.D.)

A. They were good in a very selected small group of women under observation, namely, those who were young, usually under 20, who manifested hormone deficiency in terms of ovarian function, so that not only were the breasts underdeveloped but their genital tracts were similarly underdeveloped. So that those women with hormone deficiency did respond to the topical application of estrogens to the breasts.

Q. Were there any successful results where there was no hormone deficiency?

A. None whatever.

Q. Do you have an opinion, Doctor, as to the incidence [340] of hormone deficiency in females?

A. Only an approximate idea. I would say in the range of 10 or 15 per cent of the women who present themselves to me, either at my clinics or in my private office, would have or would manifest a hormone deficiency.

Q. Only, that is, of those who present themselves?

A. That is right.

Q. And does that presuppose anything? In presenting themselves, is that any indication that they feel there may be something wrong?

A. Exactly. They present themselves to me because they are seeking help in overcoming.

Q. Then, this ten to fifteen per cent would not apply to women in general?

A. Not at all.

Q. Now, Doctor, if a woman has a small bust, does

(Testimony of Samuel J. Glass, M.D.)

that mean that she is suffering from a deficiency of her own hormones? A. Not necessarily so.

Q. Would you explain that, please, Doctor?

A. Well, nature endows us with a variety of shapes and sizes of different organs. Very much like the size of one's nose or the shape of one's foot, it is not necessarily dependent upon the sex hormones for its ultimate development. There are many women who have perfectly normal reproductive function and yet have very small breasts. Yet, those breasts may suckle, may develop adequate amounts of milk, and after nursing they may regress to their original small size. So that size alone is not necessarily a sign of failure of function. It may be a cosmetic defect but not necessarily a functional failure.

Q. Will you kindly explain, Doctor, what you mean by cosmetic defect?

A. Well, American civilization especially seems to emphasize the importance of cosmetic perfection in terms of a female bust. It is advertised, very widespread, in that regard. I think the American women particularly are self-conscious about the size and shape of their breasts.

Q. Now, Doctor, converse to your previous explanation, would it be true that a woman who is deficient in her natural estrogens likewise would have a small breast?

A. Those who are deficient may or may not manifest a small underdevelopment of the mam-

(Testimony of Samuel J. Glass, M.D.)

mary glands. They frequently do have small breasts, not necessarily so.

Q. Then, there is no direct relationship between the two phenomena? A. No.

Q. How, in what manner is it possible to determine whether or not a female human has a hormone deficiency?

A. That can be determined by the investigation of the [342] individual from many different aspects aside from the usual inventory of the patient's history, her development, her feminil background, there are certain physical stigmata that are demonstrable by physical examination, and likewise certain laboratory tests will reveal hormone deficiencies.

Q. Now, in those tests and in these matters of diagnosing a female hormone deficiency, do they require any special training, Doctor?

A. Very much training.

Q. Are there any subjective symptoms by which a woman could correctly diagnose her own female sex hormone deficiency?

A. I know of none.

Q. Now, Doctor, in your work as an endocrinologist, do you use an estrogenic substance known as alpha estradiol? A. I do.

Q. Do you consider this to be a potent substance? A. I do.

Q. Are you familiar with the use of a tablet in the strength of .5 milligrams per tablet?

A. Yes, I use such tablets.

(Testimony of Samuel J. Glass, M.D.)

Q. You have used them, you say?

A. I mean I have prescribed them.

Q. Do you know whether there are any dangers in the use of such a tablet?

A. Very specific dangers. [343]

Q. What are these dangers, Doctor?

A. The first and perhaps the most important is that of impairment or disturbance of the menstrual cycle in the female, and in so doing I believe that fertility will be impaired likewise. Secondly, there are certain females who actually manifest some degree of intoxication by an intoxication of the female hormone, literally intoxication, so that they are very uncomfortable and made sick by the hormone, and there are many manifestations of that particular intoxication. It is a broad interpretation of what happens from overdosage.

The other very distinct hazard of that is that of stimulating in the sensitive female patient various types of new growths in the female breast, in the uterus, not necessarily malignant growth but benign growths. I believe that estrogens, like the prostate in the male, will manifest acceleration of growth of any tumor, whether it be benign or malignant under the influence of estrogens over a long period of time.

Q. By a malignant tumor, would that include a carcinoma, Doctor? A. Exactly.

Q. Have you seen any such cases of acceleration of the growth of carcinoma, Doctor, in a female?

A. I have seen three.

(Testimony of Samuel J. Glass, M.D.)

Q. And how do you know, what causes your opinion that [344] this acceleration was due to the use of a female hormone?

A. Two of these patients were seen in consultation, consultation having been solicited by other physicians who gave me the history that these patients had taken estrogens over a long period of time, either by prescription or by self medication, the exact details of which escape me at this moment.

A third patient was under my own supervision during the time that she was taking estrogens and a carcinoma seemed to develop under my very own eyes.

Q. This carcinoma had some different appearance from a normal carcinoma, is that correct, Doctor?

The Witness: Your question is a little ambiguous. Just what do you mean?

Q. (By Mr. Danielson): How is it possible to determine that this has developed in a manner that is often normal, other than the normal development of such a carcinoma?

A. It is impossible to be too certain as to whether the carcinoma would have manifested itself with or without the added estrogen. It is impossible to be certain of it. But this much is true: that clinically and experimentally, it has not been possible to observe the development of cancer in the absence of estrogen; that is important; that the female who is a castrate or without ovaries will never manifest malignant growth in the bust or in the uterus if she

(Testimony of Samuel J. Glass, M.D.)

did not have it before castration. The same thing is true of the experimental animal. You cannot induce experimentally cancer growth in the experimental animal, in the absence of estrogen or ovarian activity.

Q. In your opinion, Doctor, the presence of estrogen is a condition precedent to any development of such a malignant growth?

A. It is an absolute prerequisite.

Q. Doctor, just for the sake of clarification, is the uterus a part of the female generative system?

A. A most important part.

Q. Now, Doctor, do you use estrogens in your practice? A. Extensively.

Q. Now, under what circumstances do you find that it is safe to use them?

A. Well, the first requisite is the presence of a hormone deficiency, an estrogen deficiency, and assuming that that is already present, a great deal depends upon the age of the female, whether she be in the reproductive age or whether she be in the menopausal age, because the mode of administration under those circumstances is widely different. So that the age of the patient and the condition of the patient makes all the difference as to how you give it and how much you give.

Q. Would you explain that a little more fully, Doctor?

A. All right. In order not to disturb the fertility or [346] menstrual function of a female in

(Testimony of Samuel J. Glass, M.D.)

her reproductive age, the estrogen must not be given continuously, because by the continuous administration of estrogen you interrupt the normal sequence of events that make up the monthly rise and fall that constitutes the menstrual cycle; and unless you more or less stimulate the natural sequence of events in terms of rhythmic rise and fall of estrogens, along with other hormones, such as progesterone, you will not serve your patient in any useful function.

Q. Does that require careful supervision, Doctor?

A. All of that implies the most meticulous diagnosis and supervision.

Q. In such hormone therapy, is it desirable or is it necessary to first eliminate the possibility of present cancer?

A. It is most important to eliminate that possibility, by the most careful search for any type of tumor, growth in the uterus or in the breast, because I have already indicated that estrogens will accelerate the growth of benign or malignant tumors in these organs.

Q. Over how long a period should this supervision, continual supervision, take place?

A. As long as the patient requires treatment.

Q. And what is the purpose of that continuous supervision, Doctor?

A. Obviously to prevent the interruption of the reproductive function; secondly, to avoid intoxica-

(Testimony of Samuel J. Glass, M.D.)

tion, and thirdly to avoid the stimulation of tumor growth.

Q. In other words, if such a growth were to appear, then, what action would be indicated?

A. Obviously estrogenic treatment must be stopped immediately.

Q. Will you explain a little more fully what you mean by intoxication, in this connection?

A. Well, there is a very complicated aspect of treatment. Many women present themselves already overloaded, if you will, with ovarian hormones, particularly the estrogens. I have done a great deal of research on the importance of the liver, for example, in terms of estrogen metabolism; in the presence of liver disease the estrogens are not eliminated in a normal fashion from the human body; they pile up, so to speak, in the blood and give rise to what is known as hyper-estrinism, that is, an excess of the hormones. This excess of estrogen will of itself lead to various types of intoxication.

Q. May I interrupt you one moment. Are you referring now to the woman's own natural supply?

A. Her own natural estrogens. I was coming to the point of the artificial administration.

Mr. Elson: Pardon me for a minute. Is that in issue here?

The Witness: No, I was just coming, Mr. Counsel—

Mr. Danielson: Just a moment. He is just

(Testimony of Samuel J. Glass, M.D.)

explaining [348] the term intoxication which has been put in.

Mr. Elson: That is all right. It doesn't make any difference to me, except if we are going to inject something else, some other condition that can be caused by this, other than what is put in the information, well, we are getting into an issue that isn't in the case which means that we unnecessarily prolong it, don't you think?

Mr. Danielson: Well, we will not pursue the point any further, your Honor. No further questions.

Mr. Elson: Could we have a short recess, until we gather some things together?

The Court: Yes.

(Whereupon a short recess was taken.)

Mr. Danielson: Your Honor, with the permission of counsel there is one additional question I would like to ask.

The Court: Yes.

Q. (By Mr. Danielson): Doctor Glass, you have testified as to the effect of 0.5 milligram tablets of alpha estradiol. Do you have an opinion as to what would be the effect of the administration of tablets containing .1 milligram each of crystalline alpha estradiol in this dosage, three daily for ten days and one daily thereafter?

The Witness: Well, the word "thereafter" will have to be qualified.

Q. (By Mr. Danielson): Then, one daily, without the word [349] "thereafter."

(Testimony of Samuel J. Glass, M.D.)

The Witness: —as to what duration of time the tablet will be taken will make all the difference, as to whether it constitutes a hazard to the patient or not. The dose is relatively small. On the other hand, the human economy is so constituted that there is a great deal of variability as to the response to these artificial hormones. Some respond very well to a small dose. Others require larger doses. So that everything would depend upon the actual status of that individual, as to whether the .1 milligram tablet will constitute a hazard or not. If that individual is a healthy individual and is free of cancerous susceptibility, then, administration of that kind of estrogen or that dose of estrogen over a short period of time may do no harm. Over a long period of time, it may do considerable harm.

I wonder if that is what you wanted?

Mr. Danielson: Yes, I believe that it is. No further questions.

Cross-Examination

By Mr. Elson:

Q. Doctor, you just stated that alpha estradiol in the quantities mentioned by Mr. Danielson would do harm with some women and with other women it would not. The same thing really is true, isn't it, with something that is more simple and associated with our daily life, for instance, Coca-Cola to a person who has diabetes and does not know [350] it?

A. It is a poor analogy, but I think it is acceptable. The diabetes might be impaired all the more by too much sugar.

(Testimony of Samuel J. Glass, M.D.)

Q. And the same would be true, wouldn't it, with butter?

A. Depending on what we are talking about.

Q. Well, a diabetes?

A. Oh, that is a debatable point. A good deal depends exactly on how that butter would be applied and in terms of relative proportion to carbohydrate and protein in the diet.

Q. Well, now, I do not mean to get into the discussion of diabetes, but I just simply wanted to bring that out at that point.

Now, isn't it true that the same analogy can be applied in the case of many other drugs than alpha estradiol, that are commonly and regularly sold over the counter without prescriptions, depending on the individual and some latent condition within him?

A. I don't quite see your point.

Q. Well, let us take a rather humble example, but we have used it before, Bromo-Seltzer. Bromo-Seltzer, as we know, is sold over the counter, it is dispensed by the soda fountain man at the soda fountain, but it is true, isn't it, that a person who becomes addicted to the use of Bromo-Seltzer suffers, can suffer serious consequences?

The Witness: May I make a humble confession? I don't know what is in Bromo-Seltzer. [351]

Q. (By Mr. Elson): Bromides.

A. Bromides—well, bromide intoxication from that kind of a beverage would be a very, very rare complication or very rare end result.

Q. Isn't it a fact that there are people who are

(Testimony of Samuel J. Glass, M.D.)

today mentally deranged, though they may not be in an institution (some may, I don't know), from the overindulgence of bromo-seltzer?

A. I am not aware of it.

Q. Well, isn't it *a true* that a person who over-indulges in the use of alkaline products such as alka-seltzer can in time develop alkalosis?

A. It is rather rare, very rare.

Q. Well now, let us come back to our estrogens. Isn't it a very common thing, maybe not in your practice but let us say, take the general average competent practitioner, in other words, the family doctor, isn't it a very common occurrence for women who come to him and complain of conditions, I don't know whether they are necessarily associated with menopause or not, but they complain of conditions in which he determines that estrogen is the thing that he should give them and so for a short period of time he injects them with estrogen, and thereafter puts them on a maintenance dose of tablets and gives them a prescription, and they go back to the drug store, time after time, time after time, and have the [352] prescription refilled without obtaining a new prescription from the doctor?

A. I wasn't aware of the fact that a patient is regularly apt to refill her prescription without further consultation with her doctor.

Q. Well, of course, we will assume that the patient will periodically, not at any stated intervals, return to the doctor for one reason or another, but

(Testimony of Samuel J. Glass, M.D.)

not go to the doctor every time that the box has become empty and she wants it refilled?

A. That is conceivable.

Q. Now, you stated that—I believe I am correct and, if I am wrong and if I am misquoting you, you can let me know, but I thought I heard you say that you had practically seen a breast cancer develop under your eyes from the administration of estrogens? A. Yes.

Q. Have you ever definitely and absolutely, not as a question of opinion or conclusions from other things, but absolutely demonstrated as a fact that the administration of estrogens caused an incipient carcinoma of the breast, cervix or uterus to accelerate in growth?

A. I believe those three instances of my own personal experience were vivid enough to emphasize the possibility that estrogens accelerated the growth of cancer. [353]

Q. In other words, then, it results to this, does it not, that it is from your experience, it is your opinion that possibly cancer of the breast, cervix or uterus results from the administration of estrogens? A. Correct.

Q. Well now, in this case here, we have to come back to the allegations that are contained in the complaint or in the information and those allegations are substantially this: that 5/10 of a milligram of alpha estradiol may accelerate the growth of an incipient carcinoma of the breast, cervix or uterus. Now, Taber's Dictionary defines incipient as be-

(Testimony of Samuel J. Glass, M.D.)

ginning. Do you think that you would be able to diagnose an incipient cancer of the breast, cervix or uterus, find it?

A. Of the cervix and the uterus, perhaps. Of the breast, less likely.

Q. Now, Doctor, you are familiar, are you not, with the manufacturers of hormone products in this country, Roche-Organon, Schering and Ciba?

A. I am.

Q. Now, I think the dosules that you looked at that is on the label were .002 units, were they not?

A. 2/10 of a milligram, approximately that.

Q. Now, it is true, isn't it, that those three firms maintain extensive research and control laboratories, as far [354] as you know?

A. I believe they do.

Q. And, so far as you know, the men who comprise the staff are considered to be competent men in their field?

A. The staff of——

Q. In the laboratories of those large organizations?

A. I think that is a safe assumption.

Q. It would be a reasonable assumption?

A. Yes.

Q. Now, Doctor, I am going to show you here a brochure, I guess that is what you would call it——

A. Right.

Q. ——that has to do with the dosules, the label of which you looked at this morning, and there are two pictures on there that show conditions before and after treatment with those dosules. The after

(Testimony of Samuel J. Glass, M.D.)

picture shows a considerable increase in the size of the breast, does it not?

I take it from your testimony this morning, however, that it has not been your experience that dosules of the potency described on that label produce the results shown on that picture?

A. That was my experience. If I may qualify——

Q. Surely.

A. I indicated in my response to the former counsel's last question that there is a great deal of variability in the [355] response to hormones, no matter how administered. Some individuals respond very well to a small dose. Many others do not. That particular illustration is of one of those individuals who is particularly sensitive to low-dosage hormones. [356]

Q. Well, wouldn't the same thing be true with aspirin? Aspirin will relieve some people of headaches and won't relieve others of headaches and, when one is not relieved by aspirin, he doesn't take aspirin any more, does he?

A. If that is a proper analogy—I think it is a poor one, a very poor one.

Q. Well, go ahead and think so.

A. I have an answer for an analogy like that.

Q. Counsel read to you from the pamphlet that accompanied this dosule and I find in this brochure of which I speak the following statement: "The clinical value of cutaneous estrogen therapy for the

(Testimony of Samuel J. Glass, M.D.)

treatment of underdeveloped breasts was confirmed by C. M. MacBryde, J. A. M. A., 1939, volume 112, page 1045. He states that 'Estrogens can be absorbed through the skin of the human female directly into the breast tissue and by this route can produce their characteristic stimulation of mammary growth,' and the result in his cases was 'definite breast growth of considerable degree.' Since underdeveloped breasts are often a considerable worry to women, cutaneous estrogen therapy of hypomastia represents a valuable addition to the physician's therapeutic resources."

Now, I am going to ask you, although I don't need to ask you because it is self-evident, but I would like, for the benefit of the court, to read again what Mr. Danielson did, and you will find that the language is exactly the same: [357]

" 'Estrogens can be absorbed through the skin of the human female directly into the breast tissue and by this route can produce their characteristic stimulation of mammary growth,' and the result in his cases was 'definite breast growth of considerable degree.' Since underdeveloped breasts are often a considerable worry to women, cutaneous estrogen therapy of hypomastia represents a valuable addition to the physician's therapeutic resources."

Doctor, do you disagree with that statement insofar as it applies to the use of dosules such as described on that label?

A. That requires a qualified answer, counsel. I, too, have made the observation as MacBryde, but

(Testimony of Samuel J. Glass, M.D.)

you failed to mention MacBryde uses doses far in excess of that which is possible to obtain from the dosules. You also failed to mention that these women were utterly deficient in estrogens; that they were hypogonadal females, lacking hormone, and thereby benefiting from hormone when administered through the skin or by needle or by mouth. That type of a female may respond, depending on the dose and on the degree of the hormone deficiency.

Q. Then, it would be your opinion that the language that I have just read to you, quoted from the brochure by Roche-Organon, was not a correct statement insofar as it applied to the dosules which were the subject of the brochure? [358]

A. It was an incomplete statement.

Mr. Elson: I think we might as well offer this in evidence now as our first exhibit.

Mr. Danielson: No objection.

The Clerk: Defendants' Exhibit A in evidence.

(Said document so offered and received in evidence was marked Defendants' Exhibit A.)

Q. (By Mr. Elson): By the way, Doctor, you said, I believe, in your direct testimony that you used potencies and dosules 20 times that mentioned on the label?

A. Occasionally.

Q. In other words, that would be what?

A. 10 milligrams to the gram. I have even gone as high as 20 milligrams to the gram.

Q. Incidentally, to avoid my taking the time to

(Testimony of Samuel J. Glass, M.D.)

look it up in the dictionary, what is "hypoplesia"?

A. A lack of development.

Q. I have here a book with which you are undoubtedly familiar, "Endocrinology of Women," by Hamblen.

A. I am familiar with it.

Q. The date of it is 1945. And, on page 526, chapter 50, under the head of "Tumorigenesis," the author states as follows: "The suggestion has been offered that breast carcinoma results from carcinogenic action of intrinsic estrogens, probably concomitant with functional alterations in the endocrine [359] system. Unopposed or continuous estrogens acting upon responsive tissue may cause a typical cell growth.

"Numerous clinical reports have suggested the possible etiologic importance of estrogens in carcinogenesis but in none has this relationship been proven."

Then there is a description of three cases, and the author continues:

"These three reports are of minor import when one considers the thousands of women who have received estrogens for as long or longer periods of time and in comparable or larger doses without developing carcinoma."

Are you in agreement or disagreement with the statements of the author?

A. You make many statements there. I would like to take it piecemeal, if I may.

Q. Surely.

(Testimony of Samuel J. Glass, M.D.)

A. I disagree heartily with the idea. Three cases of cancer are of no significance as a possible complication of estrogenic treatment. I do agree that in proper dosage, when properly indicated, estrogens may be of value in development of the female breast. What other aspects of the question are there?

Q. I think that covers it. By the way, do you know of the author E. C. Hamblen?

A. He is a personal friend. [360]

Q. He is considered to be an authority in the field of endocrinology, I take it?

A. Female endocrinology.

Q. By the way, it isn't at all uncommon for you folks, just as lawyers, to disagree on various subjects from time to time in their various phases?

A. That is correct.

Q. I have here a book entitled "Recent Progress in Hormone Research," volume 1, a symposium, in which one of the contributors is Dr. Ira T. Nathanson. Are you acquainted with him?

A. I am familiar with the work.

Q. Dr. Nathanson's article is entitled "Endocrine Aspects of Human Cancer," which was published in 1947. He covers tumors of the breast, carcinoma of the breast, tumors of the uterus, cancer of the cervix, tumors of the prostate gland, cancer of the prostate gland and tumors of the testes and so forth, and, finally, on page 281, under "Conclusions," he states as follows:

"A considerable number of data bearing on the

(Testimony of Samuel J. Glass, M.D.)

relation of the endocrine organs to tumors have accumulated. The administration of sex hormones to experimental animals has resulted in the production, the augmentation and the inhibition of benign and malignant tumors. These changes are limited to definite types of tumors in different species, as well as to [361] certain strains in any one species of animal. Thus, there are other factors that determine the reaction of a tissue to a hormonal stimulus, and the susceptibility of an animal to the induction of neoplasm. It is difficult to interpret these facts in terms of human cancer. Nevertheless, they are of extreme importance in the study of the origin and course of cancer in general."

Are you in accord or not with the conclusions there stated by Dr. Nathanson, after having covered the subjects I mentioned?

A. I think it is a reasonable personal interpretation of the known facts.

Q. By the way, when was it that you made those observations as to the development or growth of a breast cancer as a result of the administration of estrogens?

A. I didn't say as a result.

Q. I didn't mean to misquote you. When was it?

A. Within the last 15 years.

Q. Can you tell me within what portion of the 15 years?

A. I would say two of those were approximately 15 and 12 years ago and the third was approximately 7 or 8 years ago.

Q. Just a minute. Oh, yes; one other thing.

(Testimony of Samuel J. Glass, M.D.)

It is a fact, isn't it, that during pregnancy a woman produces more [362] estrogen than she does when she is not pregnant? A. That is true.

Q. And, as the period of pregnancy continues on, she produces more estrogen? A. Yes.

Q. Do you find the incidence of breast cancer to be present—that isn't exactly what I want to say——

A. Higher incidence?

Q. ——of breast cancer of higher incidence in women who have borne a number of children or who have borne only a few?

A. If you don't mind, counsel, the question is a little bit ambiguous. Are you implying that the concentration of estrogens during pregnancy may be a factor or may not be a factor? What are you driving at?

Q. I am not trying to be smart with you at all, Doctor. I would like to have you answer the question and then let me go from there.

A. I don't think you have stated it quite clearly enough. If you hadn't added the number of pregnancies or the nursing or what have you—just simplify the question for me, if you don't mind.

Q. Do you find that the incidence of breast cancer is higher with women who have had a number of children than it is with women who have had no children, we will say? [363]

A. I am not sure. My impression is that it is. But one very important aspect of the problem is

(Testimony of Samuel J. Glass, M.D.)

this, that during pregnancy it is a common observation that cancer of the breast grows very rapidly and for that reason women with any cancer susceptibility in their history, or who have had a cancer removed, are always forbidden to have more children.

Q. You are acquainted with Dr. Macdonald out at USC, aren't you? A. I know him.

Q. Ian Macdonald? A. I know him.

Q. Yesterday I asked him the same question and he said that the incidence of breast cancer——

Mr. Neukom: Will you refer to the record?

Q. (By Mr. Elson): On page 142 of the transcript, I asked Dr. Macdonald this:

“Q. Well, do you find in your experience that the incidence of breast cancer is greater with women who have had no children, or women who have had some children or women who have had a lot of children, or just what?

“A. I have statistical information on that subject. The incidence of cancer of the breast is distinctly greater in those women who have not borne children, or who having borne children have failed to nurse them at the breast.”

Would you agree with that statement? [364]

A. That might have been his experience. I do not claim any special experience with pregnancy because I don't see pregnant women.

Q. Did I understand you to say that there was clinical evidence, with which you were acquainted, that 5/10 of a milligram of alpha estradiol would

(Testimony of Samuel J. Glass, M.D.)

cause the acceleration of an incipient breast cancer?

A. No specific evidence to that particular dose. I think the general statement would cover it that, having cancer, that individuals manifest acceleration in the growth of that cancer if given estrogens over a long period of time.

Q. That, of course, presupposes a cancer and one which you have been able to diagnose as a cancer?

A. Yes; I know, because early cancer is difficult of detection.

Q. And an incipient cancer of the breast, keeping in mind our dictionary definition, would rarely be designated by you?

A. It frequently escapes detection.

Mr. Elson: I have no further questions.

* * *

Redirect Examination

By Mr. Danielson:

Q. Doctor, what is the meaning of [365] etiologic or etiology? A. Cause.

Q. Causes? A. Causes.

Q. Doctor, is it your opinion that the estrogens will cause the carcinoma of the breast, uterus or cervix, or that they will accelerate their growth, that is, is the estrogen carcinogenic?

A. Estrogen is carcinogenic in certain animals. It has not been proven to be so in the human subject. However, it will definitely accelerate the growth of existing cancer.

(Testimony of Samuel J. Glass, M.D.)

Q. Doctor, the remaining question is, directing your attention again to Defendants' Exhibit A, the brochure from Roche-Organon relative to the menformon dosules, counsel has read therefrom what purports to be a quotation from the Journal of the American Medical Association, 1939, volume 112, at page 1045, as follows:

“ ‘Estrogens can be absorbed through the skin of the human female directly into the breast tissue and by this route can produce their characteristic stimulation of mammary growth’ and the result in his cases was ‘definite breast growth of considerable degree.’ ”

Now, Doctor, I invite your attention to this article by Dr. MacBryde in the former-quoted entry in the Journal of the American Medical Association, at page 1049, the fourth [366] paragraph of the left-hand column, and will read the remainder of that quotation:

“It is definitely not recommended that this method be adopted in general practice until further studies can be done and the limitations and possible dangers of the cutaneous application of concentrated estrogens can be defined.”

Now, Doctor, in view of the balance of this quotation, do you now disagree with Dr. MacBryde?

A. I do not.

Q. And in the same article, in the initial paragraph, on page 1045, I read as follows:

“I have been unable to find records of carefully

(Testimony of Samuel J. Glass, M.D.)

controlled studies of human breast growth. I, therefore, performed studies on three women lacking mammary development and exhibiting signs of marked hypogonadism. In the first part of the study, the hormones were administered by subcutaneous injection. I was able to demonstrate that, by the injection of from 15,000 to 35,000 international units of estrone or of estradiol benzoate per week, active mammary growth could be produced in patients who previously had no visible or palpable breast tissue."

Doctor, in view of that, do you now disagree with Mr. MacBryde on that point?

A. I do not disagree.

Q. And does it conform with your experience in this matter, [367] Doctor?

A. Completely.

Mr. Danielson: Thank you. No further questions.

Your Honor, may we have this exhibit marked for identification as Government's Exhibit No. 17? It is a photostatic copy.

Mr. Elson: As far as I am concerned, you can put it into evidence.

Mr. Danielson: Thank you. We will accept that.

The Court: Very well: It may be admitted.

The Clerk: Exhibit 17 for the government in evidence.

(The document so offered and received in evidence, was marked Government's Exhibit No. 17.)

(Testimony of Samuel J. Glass, M.D.)

The Court: I feel sure that counsel will not object to this, in going outside of the issues here, but it seems to me necessary to inquire all I can as to the nature and the operation of estrogens.

Doctor, I believe it is so that compounds containing estrogen are put on the market, or at least in circulation, for the purposes of ointments for skin treatment?

A. Yes.

The Court: Ointments recommended for face wrinkles and that sort of thing?

A. Yes.

The Court: That is so? [368]

A. That is so and, while the concentration of those estrogenic creams is very, very small, thereby the hazard of this self medication is reduced considerably.

The Court: Does that contain the male hormone or the female hormone?

A. Usually the female, and designed for the cosmetic trade.

The Court: What about the difference, whether they contain the male or the female hormone?

A. A great deal of difference, your Honor. The use of a male hormone preparation in the form of an ointment would actually lead to certain masculinization of the female if the concentration was adequate.

The Court: And what then would be the effect on the female along that general line? It wouldn't affect the male, would it?

(Testimony of Samuel J. Glass, M.D.)

A. It would affect her adversely if the concentration were sufficiently high to make a difference in the circulating hormone balance.

The Court: Would you say that those creams are in any manner efficient in producing the effect that is sought to be secured?

A. I don't really know, your Honor, because it has been my impression that the concentration of the commercial creams sold over the cosmetic counter is very poor; that it [369] is very poorly concentrated with the hormone. They have so little that I question the value of them for anything.

The Court: That is all.

Mr. Danielson: No further questions.

Mr. Elson: I have no further questions.

* * *

(Whereupon an adjournment was taken until 10:00 o'clock a.m., July 5, 1949.) [370]

* * *

ELMER BELT, M.D.

recalled as a witness on behalf of the government, being heretofore duly sworn, testified further as follows:

* * *

Cross-Examination

By Mr. Elson:

Q. Doctor, you spoke of the Belt Urological Group. Just what is that?

A. They are a group of us working together,

(Testimony of Elmer Belt, M.D.)

all devoting our time to urology. Our offices are at 1893 Wilshire Boulevard in Los Angeles and 120 Lasky in Beverly Hills.

Q. You spoke in your direct examination of the acid phosphatase test. Would you do it, Doctor?

A. Could I do it?

Q. First, how do you spell it?

A. A-c-i-id P-h-o-s-p-h-a-t-a-s-e.

Q. You spoke of that test being a blood test, I think. [372]

A. That is right.

Q. That is used for determining the presence of cancer of the prostate, am I correct?

A. Yes.

Q. And, as a matter of fact, though, isn't that test of value only when the cancer is metastasized to the bone?

A. It is not clear that it is only when it has metastasized to the bone but certainly it seems to be more definitely positive when metastases have occurred generally and particularly to the bone.

Q. I have here a couple of text books, with which you may be familiar. "Metastasized" means what, for the record, please?

A. It means little groups of cells have sailed over in the blood stream and growing independently of the original source. It could be lymphatic it has gone through and they could float in the peritoneal fluid.

Q. But "metastasized" means ordinarily that it has attached itself to the bone in some way?

A. No; that is not correct. The bone might have escaped. It doesn't necessarily mean that it

(Testimony of Elmer Belt, M.D.)

has attached to the bone. Metastases may extend to other regions than the bony framework.

The Court: Is that applicable to any other kind of cells or germs other than cancer? [373]

The Witness: We speak occasionally of metastatic spread of infection.

The Court: That is what I meant.

The Witness: Yes.

The Court: "Metastasis" means a group moves outward?

The Witness: That is right; that it has left the original site and has gone elsewhere.

Q. (By Mr. Elson): In other words, it has left the prostate and gone to other parts of the body?

A. Yes; that is right. It is possible, however, to have a rise in acid phosphatase in cancer of the prostate with only the local area involved.

Q. I have before me here a book entitled "Clinical Biochemistry," by Cantarow and Trumper, Third Edition. Are you familiar with that?

A. No.

Q. It was published in 1945. And, on page 201, at the bottom of the page, the author states, "Serum acid phosphatase determinations have been shown to be of clinical value only in carcinoma of the prostate, with metastasis." Do you agree or disagree with the statement of the author?

A. That is not wholly in accord with my experience but nearly so.

Q. During the course of this testimony we have referred to Volume 1, "Recent Progress in Hor-

(Testimony of Elmer Belt, M.D.)

mone Research, Proceedings [374] of the Laurentian Hormone Conference." Are you familiar with that work?

A. I am familiar with the Laurentian Conference but I haven't seen their reports.

Q. The Laurentian Hormone Conference is one of the top organizations or groups of its kind in connection with hormone investigation, is it not?

A. Yes, sir; that is right.

Q. Do you know Dr. Ira T. Nathanson?

A. I don't know him; no.

Q. Do you know of him?

A. I have heard of him; yes.

Q. He is considered to be one of the top cancer men in the country, is he not?

A. I am not acquainted with him but he has the reputation.

Q. In this volume, which appears to be a symposium, is an article entitled "Endocrine Aspects of Human Cancer," by Ira T. Nathanson. In that he discusses carcinoma of the breast, tumors of the uterus, cervix, of the prostate gland, and cancer of the prostate gland. Will you read, on page 281, the Conclusions there? Will you read that, please, and then I will read it for the record.

A. Do you want me to read here?

Q. Just read under "Conclusions." [375]

A. Shall I read it out loud?

Q. Yes.

A. "A considerable number of data bearing on

(Testimony of Elmer Belt, M.D.)

the relation of the endocrine organs to tumors have accumulated. The administration of sex hormones to experimental animals has resulted in the production, the augmentation and the inhibition of benign and malignant tumors. These changes are limited to definite types of tumors in different species, as well as to certain strains in any one species of animal. Thus, there are other factors that determine the reaction of a tissue to a hormonal stimulus, and the susceptibility of an animal to the induction of neoplasm. It is difficult to interpret these facts in terms of human cancer. Nevertheless, they are of extreme importance in the study of the origin and course of cancer in general.

“Strong evidence exists to indicate that endocrine factors are associated with some human tumors. There is as yet no conclusive proof that these influences are directly concerned with cancer, although an increasing number of cases are coming to light in which cancer developed after intensive estrogen therapy in organs such as the uterus and breast, which are normally stimulated by these hormones. It is possible that this is coincidence, but the association cannot be ignored. Present evidence suggests that the sex hormones are not in themselves carcinogenic. It is likelier that, as [376] a result of excessive stimulation of a typical metabolism, the tissues of susceptible persons are conditioned to the action of a carcinogenic agent.

“The administration of hormones or the alteration of the hormonal or metabolic status of the host

(Testimony of Elmer Belt, M.D.)

by castration may exert a profound influence on cancers of the breast and prostate glands. The fact that alterations occur should lead to intensive investigation regarding the mechanism of regression and progression in these tumors. The concept of autonomy of the cancer cell in general must be revised in light of these recent observations.

“There is no question that castration or hormonal administration have been of great benefit, as an adjunct to the treatment of a number of advanced cases of cancer of prostatic or mammary origin. Such treatment should be reserved for palliative purposes only, since there is at present no substitute for established methods in the operable patient. There is little to support the therapeutic value of castration or hormones in any other type of cancer.” [377]

The Court: Who wrote that and when?

Mr. Elson: Dr. Ira T. Nathanson, in 1947—or 1946.

Q. Do you agree or do you disagree with the statement of Dr. Nathanson?

A. In general, that sounds like good sense.

Q. You are familiar, of course, with the volume known as “New and Non-official Remedies?”

A. Yes, sir.

Q. And it is true, isn't it, that that is a standard work that is accepted by doctors as a standard work on the subject of the remedies and the drugs that are contained in the volume?

(Testimony of Elmer Belt, M.D.)

A. It is a ready means or quick reference and available guide on drugs which have not yet become definitely standardized in use.

Q. And it is true, isn't it, that that book is published and revised from time to time by the Council on Pharmacy and Chemistry, of the American Medical Association?

A. That is right

Q. And it is true, isn't it, from your experience and contact with other doctors, that it is relied on as authoritative?

A. Yes, but it is understood that it is always behind really accepted therapy; I mean in arrears; not yet caught up with. [378]

Q. Doctor, have you examined in "New and Non-official Remedies," the volume of 1948, the subject of "Testosterone?"

A. No; I haven't had occasion to consult that.

Q. I am going to show you "New and Non-official Remedies, 1948," commencing at page 410, and going over to page 411, discussing testosterone propionate and methyl testosterone and ask you if, after having read that, you find any contra-indication in there for the use of testosterone in cases of prostatic cancer or the like or anything else.

A. Your question regarding this was what?

Q. After having read that, do you find any contra-indication in the volume concerning the use of testosterone, in any form, in the case of cancer of the prostate in any stage?

Mr. Neukom: That speaks for itself.

The Witness: No; this doesn't purport to discuss

(Testimony of Elmer Belt, M.D.)

cancer of the prostate and it doesn't mention it.

The Court: It is really silent on the matter?

Mr. Elson: That is correct.

The Witness: Yes. It has a description of the drug and its method of administration and the dosage.

Q. (By Mr. Elson): Isn't it true that in many instances contra-indications are mentioned in that volume concerning drugs? [379]

A. Yes; in that volume and in that paragraph it mentions the contra-indication of destruction of the tubular epithelium and the production of azoospermia.

Q. And what is azoospermia?

A. It abolishes sperm from the ejaculate, sperm being the male sex cell which fertilizes the female, and in one paragraph it says that in young individuals the use of that material destroys that function temporarily. [380]

It doesn't happen to mention cancer. Those men who write that don't purport to set up all of the factors surrounding each of these drugs. If they did, it would take a volume of that size to cover the field of each one.

Q. The portion you speak of covering azoospermia is as follows: "However, continued administration of testosterone may induce azoospermia even though no mention of permanent suppression has yet appeared?" [381]

A. Yes; that is right. But in that they are

(Testimony of Elmer Belt, M.D.)

mistaken. Evidence of permanent suppression has appeared.

Q. Doctor, is there any test for the purpose of detecting an incipient cancer of the prostate?

A. An incipient cancer?

Q. Yes.

A. Well, let's clarify what you mean by "incipient."

Q. I don't know, Doctor. I am using the language that is contained in the information or the complaint here. It is charged that testosterone may accelerate the growth of an early or incipient cancer of the prostate. And, in looking up "incipient" in Taber's Dictionary, it defines it as "beginning." That is about as far as I can go. That language has been chosen by the government. And I would like to know from you if you know of any test whereby an incipient cancer of the prostate can be detected.

A. Well, a beginning cancer would indicate that it has already begun and there are tests which show the presence of a cancer of the prostate if it has already begun.

Q. The acid phosphatase test?

A. That would require having the prostate cancer progress to a greater extent than can be determined by other tests, namely, merely simple palpation of the gland across the rectum—

Q. Pardon me for interrupting you. If you did find [382] it on palpation of the prostate, it would no longer be incipient, would it?

(Testimony of Elmer Belt, M.D.)

A. It might be considered incipient or beginning because you can get around it and cut it out and stop it. In other words, it is not ended. To continue with your first question, you were speaking of tests. There are two tests which are already known but not in current use for very early cancer. Charley Huggins has one, which is a test of the proteins of the blood serum.

Q. How recent is that test?

A. He announced it about two months ago and it is not yet in current use. And then at Birmingham another one has been developed. By "Birmingham" I mean the local military hospital here in Southern California. These two tests are closely correlated and they resemble the Wassermann test in their reaction. They are specific protein reactions and they don't show cancer only but other devastating diseases. Their effective use clinically will come about because only when these other diseases are pretty well advanced and therefore recognizable do they affect the test in the same way that cancer does. We are looking forward with much hope to these tests but that is for the future.

Q. Assuming that a man let us say in middle age, 45 or 50, came to a general practitioner and stated that he was troubled with sweats, nervousness, and he didn't seem to remember [383] things like he used to, that he couldn't concentrate on activities, and he always seemed to have a tendency to evade them, and so on, and the doctor was of the opinion, after these symptoms were told to him.

(Testimony of Elmer Belt, M.D.)

that testosterone might be of benefit, what, in your opinion, would the general practitioner do before prescribing testosterone to this man for such symptoms?

A. Well, in the first place, he would think.

Q. Pardon me?

A. In the first place, he would be very apt to think about the problem and, if he thought about the problem very much, he probably wouldn't prescribe testosterone for those symptoms.

Q. Why?

A. Because they don't indicate hypogonadism.

Q. Is it only in hypogonadism that testosterone, in your opinion, is effective?

A. Virtually only.

Q. Hypogonadism, again, is what?

A. A reduction in the amount of testosterone created by the individual, below the level of his needs.

Q. Is it your opinion that testosterone is not of benefit to men, we will say, in that general age bracket, who have complained of those symptoms?

A. I would think it might even be harmful because it [384] would put their trust in a remedy which was not effective and probably would not strike at the source of their trouble. A very careful analysis of that problem would be needed for that patient and he would be very apt to get it at the hands of an alert general practitioner. Probably he was overworked.

Q. Isn't it a fact it is common practice, though,

(Testimony of Elmer Belt, M.D.)

among general practitioners at least, to prescribe testosterone for a man who complains of those symptoms and prescribe it for a period of say three or four weeks and then wait and see whether or not the man has been relieved?

A. I think that would be a pretty loose method of detecting it, although it might happen in the welter of a day's work. I can imagine that a man might take that shortcut but, if he really thought about the problem and got down to business and studied it, he would be concerned, first, about the psychic factors in such an individual and, second, whether he is overworked or not and troubled. Those are psychogenic symptoms you are relating when they relate to men.

Q. Do you think that a general practitioner would conduct any tests, though, before prescribing this for him?

A. If he decided on the use of testosterone for such an individual, would he conduct any tests?

Q. Yes.

A. The thing he would do, most certainly, is make a digital examination of his rectum and feel the back of his [385] prostate because, if there is a malignant process there which he could recognize, he would certainly fan it into a general fire and spread it by the use of testosterone propionate, and I think he would be somewhat reprehensible, at least not acting in accordance with the general custom of the day, if he didn't do a rectal.

(Testimony of Elmer Belt, M.D.)

Q. Would he make any blood or urine tests or anything like that?

A. For that specific question, "May I give testosterone to this patient with a certain degree of safety," there would be no blood test that he would need do unless he wished to do the acid and alkaline phosphatase test. The urine test wouldn't show him anything unless he wished to take the time to give a test for what we call the 17 ketosteroids. The 17 ketosteroids are put out by a male in a certain definite amount and we can measure that amount and determine whether he is suffering from hypogonadism.

Q. Do you think that good practice would require such a man to determine by the 17 ketosteroids test whether the man was suffering from hormone deficiency?

A. Certainly good practice would but he wouldn't be too reprehensible if he didn't do that. If he really wanted to find out if the man had hormone deficiency, that is what he would do and also the acid phosphatase test for cancer of the prostate. The acid and alkaline would show because they [386] are both involved. There are two separate tests there done up in the same bundle. But it is quite probably that, if the general practitioner decided that this was quite likely a hormone deficiency that the individual was suffering from, he would do a rectal examination and then proceed with the use of his testosterone in that individual.

Q. And then wait and see whether or not those

(Testimony of Elmer Belt, M.D.)

symptoms that the man complained of were relieved?

A. Well, he would see that they were not relieved.

Q. He what?

A. He would see that they were not relieved, and then he might begin to think about the problem. But that isn't, in general, the way our general practitioners go about their work. They generally try to solve the problem first and then apply therapy to it. There are so many things you can apply in this modern-day medicine that, if you start out and say, "I will try this drug and the other drug to see which one clicks with this patient,"—the thing to do is to take a history and make a physical examination and determine for what reason this was being used, or I mean what material should be used, and use it with some semblance of reason. Actually, that is the way most doctors think.

Q. However, the general practitioner, of course, would not approach the problem with the same precision that a man who was a specialist in that field would, would he? [387]

A. That problem is the specialty of the general practitioner that you are posing there. You are presenting a middle-aged man who is tired and worn out and who has come to the doctor for some help. That is the general practitioner's meat. He sees that every day, and he must help that fellow. Otherwise, his standing in the neighborhood would drop and he wouldn't have the reputation that he wants

(Testimony of Elmer Belt, M.D.)

in the group he is serving, and, if he prescribes an expensive remedy, and it doesn't do the patient any good, there is a doctor across the street.

Q. In other words, the approach of the general practitioner to the problems of the patient is quite different from the approach of a professional investigator or researcher?

A. I am confused by your question. The researcher is doing research on a problem and his approach is not the clinical approach necessarily. Is that what you are saying?

Q. Yes.

A. But, when he has a patient before him, then he is a clinician. For instance, in our group we are doing a considerable amount of research on a specific problem but we don't see every patient, that comes into our office, in the light of that problem. And that is the way of a research individual who is also treating patients.

Q. In your direct testimony the other day, the following question was asked of you at page 247, commencing with [388] line 12, "You feel that such precautions are a prerequisite to any testosterone therapy then, is that correct?"

A. That is right except in groups where cancer of the prostate is not liable to occur and by that I mean the cases in which testosterone is particularly valuable, or the groups of young individuals who show a definite endocrine deficiency in regard to testosterone and who need the substance in the normal process of their growth and development."

(Testimony of Elmer Belt, M.D.)

Now, I was wondering, when I read through that, what you meant when you said—well, I will show it to you. There is the question at line 12 and also down in here. I was wondering what you meant when you said, “I mean the cases in which testosterone is particularly valuable.” [389]

The Witness: Well, I think we had already talked about the boys who had their testicles blown off in the war.

Mr. Elson: I don't know whether that preceded that or not.

The Witness: I don't know. Then, following immediately, you went right on and developed that point.

Mr. Elson: I did not.

The Witness: Yes.

Mr. Danielson: I believe if the witness could see the bottom of page 246, the paragraph immediately preceding would be more intelligible, probably.

Mr. Elson: All right. I think it started at line 21, don't you?

Mr. Danielson: Well, the bottom part of 246.

Q. (By Mr. Elson): Will you read that on through there, Doctor, over on to page 247? Then I would like to know what you had in mind.

A. “During the last war, we had a large group of fellows who lost their testicles from land mines. On land mines they stubbed their toe——”

Mr. Elson: No. Turning back to pages 246 and 247, which precedes that.

(Testimony of Elmer Belt, M.D.)

Mr. Danielson: Let us say line 17 at page 247.

Mr. Elson: Line 17 at page 246. [390]

The Witness: "Q. You have mentioned that you have used methyl testosterone or testosterone in some of your treatment. Are there any instances that you know of in which methyl testosterone or testosterone can have a good effect?

"A. There are many instances in which it is a drug" of great value.

Now, you want to know what case it is valuable in?

Q. (By Mr. Elson): Yes. You said by that you mean, there at lines 14 and 15 on page 247, the cases in which it is particularly valuable. What cases did you have in mind in which it is particularly valuable? A. Hypogonadism.

Q. What type of individual is included in that category?

A. Well, individuals in which the doctor feels that the testicles are not performing their proper function, supplying an adequate amount of testosterone.

Q. Would that be the individual whose testicles had not descended or developed as a normal person's would?

A. It is not used in undescend of the testicles, because really you can't feel the—an undescended testicle may be out of reach of palpation, you don't know how big it is or how well it is performing its function from judging by its size, it would not strictly mean undescended testicles; it would mean unde-

(Testimony of Elmer Belt, M.D.)

veloped testicles and undeveloped genitalia, [391] and, given a young individual whose testicles are not up to standard, up in size and whose function is not up to standard and size, a careful administration of testosterone will increase the size of the testicles and of the penis. There is a certain penalty which is paid for that. As you know, bone growth is not complete in youngsters. They are developing in youngsters as they advance. Now, this bone growth will develop despite the fact that the child does not have adequate testicles. As a matter of fact, sometimes it develops that by testosterone propionate given in those early years, it will cause a fixation of the bone growth and we have a young individual who is stunted in his height and length of his arms. So, all that kind of thing has to be taken into consideration and the judgment of the doctor applied as to how much he wants to stimulate the testicles and how much he wants to retard the bone growth.

* * *

Q. It is true, isn't it, that you encounter from time to time young men or boys who have no growth of hair, we will [392] say that they have reached the age when they should have——

A. They have reached the age when they should have and they don't have it.

Q. (Continuing): ——and they don't have it; there is very little pubic hair, is that correct?

A. That is right.

Q. We will say there is little or no trace of any

(Testimony of Elmer Belt, M.D.)

hair on the body such as you might expect with the normal male; would a person like that be included in the class of a hypogonad?

A. Of course, what you really mean is that the sexual distribution of hair is lacking.

Q. Yes, secondary sex characteristics, would that be right?

A. Yes, other than hair growth, because it is another type of alopecia generalis, a case of general baldness.

The Court: Just a moment. Hasn't race and climatic environment much to do with that matter?

The Witness: Yes.

The Court: In the growth or development of hair on the male body?

The Witness: That is right.

The Court: Take the Indians.

The Witness: That is right.

The Court: Take the Eskimos; take people of the tropical [393] regions, they don't have hair on their bodies as the Caucasians and the others do. Take the Ainus, one of the islanders of Japan in the north, they are as hairy as a dog. Do you mean that this matter of hormones has anything to do with the difference between those people?

The Witness: I don't think so. No, not in that sense. I don't think the sex hormone determines racial differences of that type, but I was taking it that way. I think that his question eliminated that feature.

(Testimony of Elmer Belt, M.D.)

Mr. Elson: It did.

The Witness: For instance, a Negro does not have hair, the colored man has wool and his wool is distributed quite peculiarly, you don't find it on his forearms and on his chest the way you do on the white man and, as you say, the Ainu grows in the same territory as his Japanese brother, and the Japanese find it difficult to grow a beard, whereas the Ainu grows one down to his knees and he is proud of it.

To be sure, with hypogonadism, one of its indications is failure to grow hair, at the time when hair should appear, and testosterone propionate could be expected to stimulate the growth of hair in those individuals. It might not.

Q. (By Mr. Elson): Now, these blood tests and the urine tests to determine whether or not there is a hormone deficiency—not the blood test but the urine test to determine, I take it, whether or not there is a hormone deficiency and the [394] acid phosphatase test, the blood test to determine whether or not there is a cancer of the prostate that can be detected, how long do those tests take to complete?

A. The acid phosphatase test, if you are set up for it, you can complete in just a few minutes. It does not take very long.

With the 17 ketosteroid test, in the first place you have to collect a 48-hour specimen of urine, so there is 48 hours.

In the second place, it takes the chemist another two days to do the test and then he has to get his

(Testimony of Elmer Belt, M.D.)

report to you, so you have to allow a week for that.

Q. But the blood test takes how long, you say?

A. Just a very short time.

Q. The general practitioner, I take it, is not equipped to make either of those tests, is he?

A. No, no.

Q. As a rule?

A. No, he is not. As a matter of fact, in our very extensively laid out office, we don't do the 17 ketosteroids. At present, we are sending them over to Cal Tech.

Q. Now, you also stated in your direct examination, on page 253, lines 4 to 12, "There are a few special cases in which testosterone propionate is stimulating and of value over short periods of time, and that applies to methyl testosterone taken by mouth, too." What did you mean; what did you include [395] in those special cases, Doctor?

A. Well, I am not sure that what I am about to say would be generally recognized as good practice, by everyone who has thoroughly studied this problem, but what I had in mind there and what I believe myself, personally, from my own observations, is in regard to several definite symptom complexes. Now, every physician is constantly making observations which are different from those of his fellows, and that is what makes medicine grow.

A little while ago, Dr. Hans Selye of Montreal, in his experimental laboratory, showed that testosterone propionate caused a very good growth of epithelium in nephritis, in cases in which the kidney

(Testimony of Elmer Belt, M.D.)

was robbed of some of its secreting service by disease, that testosterone propionate helped this kidney to come back to function. He carried that work into the clinic from his laboratory, where the observation had been made that an animal given testosterone propionate immediately after poisoning with mercury bichloride, deliberate poisoning to damage the kidney, that the animal would require twice as much mercury of bichloride to cause its death if testosterone propionate were used as an antidote for the poison afterwards. So, picking up that little bit of information that Hans Selye put out in his experimental laboratory work, we applied it further in nephritis cases and found that these young nephritics who were just beginning to show manifestations of nephritis, a [396] disease in which the kidney is poisoned by some poisons in the body little understood, that these patients did very well with testosterone, in fact much better than the controlled cases which were treated alongside of them without it. So I had that in mind. Now, that has been verified in the literature. Other men have noticed it, but in general it is not used for that purpose probably because of its latent dangers.

Now, another group of cases in which we use testosterone propionate, for short periods of time and under controlled observation, is with the elderly man in hospital who becomes disoriented and wakes up in the middle of the night and can't recall where he is and gets up out of bed and is apt to walk down the corridor with nothing on or get into bed with

(Testimony of Elmer Belt, M.D.)

someone else, and who is mentally disturbed. That isn't funny. That is a tragic circumstance. Now, I think it is valid to use testosterone propionate in that kind of a condition. We use other measures, too. We have them breathe oxygen for 20 minutes before they go to sleep, to thoroughly oxygenate their tissues. That is general practice—that is common practice. Testosterone propionate is not used commonly for that, but we use it for that.

Another condition in which we have noticed improvement are these indolent ulcers, of the age in which the leg, the lower leg, has ulcers in it which do not heal up despite everything you do; we find that in a short period of time testosterone [397] propionate brings about sufficient regrowth of tissue to heal over those ulcers. I think that is an observation that is common to many physicians.

Those were some of the things that I was thinking of when I made that statement.

Q. (By Mr. Elson): Now, coming back here to the practioner to whom a man comes, and we will say a man in middle life, and complains of these symptoms that we have mentioned before——

A. You mean hot flashes in a male, a male who is tired, who doesn't sleep or is excessively worried and feels that he is not sufficiently combative?

Q. Yes. The doctor gives him a rectal examination, is unable to detect the presence of anything suspicious from the standpoint of cancer of the prostate, he prescribes methyl testosterone for the man, and the man goes out and fills the prescrip-

(Testimony of Elmer Belt, M.D.)

tion; it is a fact, is it not, that that man can go back to a drug store as often as he desires and have that prescription refilled, without going to that doctor or to any other doctor and having a new prescription made up for him?

A. Yes, in California that is a fact. Now, that is not the only fact. He doesn't have to have a prescription in the first place.

Q. Well, that is true, too. [398]

A. It is true, too.

Q. But even where he has gone to the doctor and the doctor has told him that he will prescribe, and he does prescribe, methyl testosterone for him, the result is just as I have said, he can go back and have it refilled as often as he wants to, without ever seeing another doctor?

A. That is right. That is the grave danger.

Q. Now, on page 253, lines 7 to 12——

A. Or the doctor could circumvent that, if he wished, by just putting a little phraseology on the bottom of the prescription, "Don't Repeat."

Q. Is that common?

A. I suppose it isn't. The doctor forgets to do it. The druggist isn't bound to observe it. Now, what is it you want me to see?

Q. Wait just a minute. Let us pursue that just a little bit further.

Now, then, Doctor, you know of course that the man can have this refilled. Is it common practice for the doctor to state on his directions to the druggist that this product shall only be taken for a

(Testimony of Elmer Belt, M.D.)

certain period of time, in order that any untoward effects from it may be diagnosed by the doctor?

A. No. That would be extremely uncommon practice. What the doctor would do is he would write at the bottom of the prescription, in Latin, "Do Not Refill." [399]

Q. And that is not common?

A. Well, I don't suppose it is. It is not common enough. Sometimes the doctor explains these matters to the patient and obtains their sympathetic understanding of their problem, but there again you are up against the difficulty that even the alert patient does not understand everything the doctor tells him. It is common experience for a physician to patiently explain a problem to a patient and have him fail to understand it.

Q. At page 253, line 7, you said, "What I am pleading for in this case is that it be adequately controlled," that is, testosterone, "with careful observations, in order not to run the patient into danger, because the good advantage this material does is out of all proportion in relation to its harm. The amount of potential harm it has is much more than the good it can do if used unbridled."

Now, what you had in mind there, when you said what you were pleading for in this case, is that the requirement be made that this product be sold only on prescription? A. Yes.

Q. Now, you know of Roche-Organon Company, do you not? A. Yes, indeed.

(Testimony of Elmer Belt, M.D.)

Q. Do you know of Ciba Pharmaceutical Company? A. Yes.

Q. And the Schering Corporation? [400]

A. Yes.

Q. By the way, as a matter of fact, Schering Corporation is owned and operated by the United States Government, isn't it?

A. My goodness, I did not know that.

Q. Isn't it one of the companies that had its origin or control with the I. G. Farben Company in Germany taken over by the Alien Property Custodian?

A. It seems to me that I read something of that sort, but you are far beyond me there.

Q. Now then, Doctor, so far as you know, these companies maintain research staffs?

A. Yes. Ciba, for instance, invented DDT.

Q. And, so far as you know, the gentlemen who comprise those research staffs are competent men in their field?

A. They get the best people they can get.

Q. I beg your pardon?

A. They get the best men they can get. They are continually robbing our laboratories of men like Charles Huggins.

Q. It is true, also, that these three large companies distribute great quantities of literature explaining to the physician the use of their products, do they not?

A. Very elaborate literature, beautifully illustrated.

(Testimony of Elmer Belt, M.D.)

Q. And isn't it a fact that the average doctor relies considerably on the statements that are contained in that literature, [401] as well as the contra-indications that are made?

A. Well, we have a phrase, *cum grano salis*, which we use there, I suppose.

Q. I have forgotten all the Latin I ever knew.

A. Until you get into legal verbiage, but that means with a grain of salt.

For instance, one company makes penicillin, and a brochure lies on my desk right now for that company's penicillin and its great efficacy in the treatment of syphilis. But it does not say anything at all about the other materials which are used in the treatment of syphilis and indeed used to much greater advantage in connection with this penicillin of theirs. Here is this beautiful brochure and it leaves out a very essential fact that one of their associates these days ever used an agent during the course of this treatment which will make better and more efficacious the use of their own product. That is the kind of thing one must be aware of, if he is listening to only one approach. Every practitioner realizes in reading the literature of a protagonist of one firm's substance, that he is reading biased literature and if he wishes to obtain real information, he can go to the original sources.

Actually, what the practitioner finds in reading this type of literature you are speaking of, advertising literature, is that the bibliography given at the end of [402] each of these articles is one of the

(Testimony of Elmer Belt, M.D.)

most valuable contributions of the person that he has before him, and he usually goes over to the library and has that material laid out for his use, so that he can control these observations by going back to their original sources, and it is just as you can read one paragraph and pervert the mind of your audience with that, you may find out that this company is using an isolated fact, which when read further is mitigated by other observations.

Q. Now, do you think that the average doctor has the time in which to run down that bibliography? And see whether or not it supports the text in the manufacturer's brochure?

A. Well, I am the director of the Los Angeles County Medical Library, the County Medical Association Library. It is astonishing the number of doctors that use that.

Q. You think that they do that? A. Yes.

Q. Do you think that doctors in reading this literature assume that the manufacturers have left out certain factual or important information on the subject in the brochure?

A. Oh, we know it so well.

Q. And the average doctor feels that way?

A. Oh, yes.

Q. The same would be true of contra-indications?

A. Oh, I suppose they would be very careful not to turn out a really poisonous product that a doctor would get into trouble with, if they could avoid it.

Q. Now, I am going to show you——

(Testimony of Elmer Belt, M.D.)

A. (Continuing): They might fail to list contra-indications properly, they might very well fail to do it. Again, there are little and big companies you know, and there are small companies which do not have the funds to carry out concepts like this, who are apt to give misinformation, that the large companies would not put out.

* * *

Q. (By Mr. Elson): Now, I have here a handbook, Schering Handbook, that I have shown to counsel, 1947 edition, and I refer to pages 11 and 12 dealing with Oreton, the trade name of their male sex hormone, and ask you, Doctor, to read that, please, and state whether or not you find anything there that contra-indicates that product in connection with an incipient cancer of the prostate or any kind of a cancer.

A. (The witness examines said handbook.)

Now, you wanted to know what, after I read this?

Q. Whether there is anything on those two pages that you read that contra-indicates the male sex hormone in [404] the case of an incipient cancer of the prostate or any other kind of cancer.

A. No. There is more than that, though, that I disagree with in this.

Q. Just a moment. The answer is you do not find anything like that?

A. That is right.

* * *

Q. As a matter of fact, I am willing to introduce the handbook in evidence.

(Testimony of Elmer Belt, M.D.)

A. The answer to that question is no. What date is this?

Q. 1947.

A. That is already two years old.

Q. That is, I take it that it is 1947, copyright 1947.

A. Yes.

The urogenic nature of testosterone propionate in elderly men was known before this thing was gotten out but, as I said before, here are two little passages and while you can't get [405] everything in here, they do say, "In elderly males, suffering with disorders in which unusual activity may be hazardous; a contra-indication."

Q. That is right.

A. Of course, that is a sort of come-on paragraph, because it makes the person reading it feel that surely this elderly male will have his sexual appetite, interest and ability to perform so stimulated that he will kill himself having sexual intercourse.

Q. And that is under the heading, though, of "Contra-indications," isn't it?

A. Yes, but it has that reverse implication which is very bad. It doesn't do any such thing. The French call that the sweet death. [406]

* * *

The Witness: All right. There is more, though, that is disastrous there, besides that. For instance, he refers all the way through to the male climacteric. I don't think there is any such thing.

Q. (By Mr. Elson): Pardon me?

(Testimony of Elmer Belt, M.D.)

A. He refers on those two pages, all the way through, to the male climacteric. I don't think the male has any climacteric. I think that most careful observers believe that, also, that there is no male climacteric.

Q. Well, isn't it true that that opinion that you have just expressed is one that is not universally shared by the profession?

A. Goodness. I don't know of any opinion that is universally shared by my profession or yours.

Q. Doctor, I agree with you. And it is also true, is it not, that there are many, many articles that have been written in medical journals on the subject of male climacteric?

A. In proportion to the number of loose thinkers that there are.

Q. Do you know Dr. August Werner?

A. Not wisely, but too well. [407]

Q. Of St. Louis? A. I know him.

Q. Do you consider him to be a loose thinker?

A. Yes, he is an example of the type of person who gets all mixed up in this problem and mixes up psychogenic problems, psychosomatic problems, with physiological ones and I think it is very bad.

Q. Do you know Dr. Hans Lissner of the University of California Medical School?

A. Yes. He was one of my teachers and, to a certain extent, he does the same thing.

Q. He is one of those loose thinkers?

A. To a certain extent.

Q. Do you know Dr. Escamillo?

(Testimony of Elmer Belt, M.D.)

A. I believe he is an associate of Hans Lisser.

Q. Do you consider him to be a loose thinker?

A. I think that some of the articles that they have put out on this subject are bad.

Q. Well, there is no use of taking the time to go into them all, but it is a fact that many, many articles have appeared in the Journal of Urology, the Urological and Cutaneous Review, and other similar medical journals in which various doctors have discussed the male climacteric, its symptoms and treatment, and so on?

A. The majority of the articles discuss it only to show [408] that it doesn't exist. There are a few individuals who believe that there is a male climacteric, but I think that the best thought is to the contrary. As a matter of fact, in Hollywood we say that a woman has a change of life but a man has a change of wife.

Q. Do you know Dr. Lester Hollender?

A. No, I don't.

Q. Dr. Harold R. Vogel? A. No.

Q. There is a publication, is there not, entitled The Archives of Dermatology and Syphilis?

A. Yes, sir.

Q. Was that considered to be an authoritative publication?

A. Yes. All of these are authoritative publications that you have mentioned, but they don't keep out articles because they present views which are contrary to the current accepted opinion.

Q. Well, without taking the time to go into all

(Testimony of Elmer Belt, M.D.)

of these things, it is true, now, isn't it, as a fact, that there have been many articles written by many doctors in these various publications in which they discuss the male climacteric, its symptoms and how it is to be handled and treated in connection with testosterone?

A. I suppose one could, on combing the literature for [409] that purpose, uncover numbers of them.

It is also true that in the two processes, the menopause in the female, that process is nothing like that which occurs in a man; the ovary atrophies, the menstrual cycle stops, the whole status of the woman changes.

Q. Doctor, I have just shown this little pamphlet to counsel, another publication of the Schering Corporation, a publication of the Medical Research Division, and entitled "A Rational Approach to the Treatment of the Male Climacteric," published in 1945, and ask you to read at the bottom of page 11 under the title "Genitourinary Effects," over to the end of that title on page 12.

Would you read it aloud? Then it will save me reading it later.

A. "Impotence, as a manifestation of the male climacteric is often amenable to androgen therapy and, as Lamar indicates, 'Sexual powers and libido can be restored in a moderate degree, bringing in many cases, peace and renewed marital happiness.'

"Urinary difficulties due to prostatism respond favorably to Oreton."

Prostatism is another field.

(Testimony of Elmer Belt, M.D.)

“Kearns observed ‘a definite beneficial effect in the improvement in tone of the bladder as noted in cystometric measurements and in the detrusor action as evidenced by a better [410] emptying power and smaller amounts of residual urine. Subjective relief from frequency and dysuria has been noted consistently. The majority of the patients have also noted varying degrees of improvement in the urinary stream.’”

Q. Now, Doctor, do you agree or disagree with the statement that you have just read there concerning the subject of impotence?

A. I disagree with it.

Q. Do you know Dr. John R. Rand, of Portland, Oregon?

A. Yes.

Q. He was one of the urologists that recently attended the American Urological Association meeting here in Los Angeles, in May of this year, was he not?

A. Yes, I believe he was here. I don't recall having seen him but I think he was here.

Q. Now, Dr. Rand was reported to have said, during or at the conclusion of that meeting, “We don't believe that men get cancer from taking male hormones or that women get other forms of cancer from taking female hormones.”

Mr. Neukom: Wait a minute. Is that in a publication?

Mr. Elson: No.

Mr. Neukom: Is that in a publication?

Mr. Elson: No, no. He was reported to have said that. Let me go ahead.

(Testimony of Elmer Belt, M.D.)

Q. Did you hear Dr. Rand make such a statement? [411]

A. No, I did not hear him. That could be logical.

Q. For the purposes of the question only, let us assume that he did make it, would you agree or disagree with such a statement?

A. As far as that statement goes, I could agree with it. I don't believe they can get it that way either. I believe they already have it, that it would not grow and disturb them, and that the hormone causes it to grow and overflow out of bounds.

Q. That makes me think of something else. All men produce testosterone, do they not, men who have not been castrated? A. Yes.

* * *

Q. Can you say with any given individual the amount of [412] administered testosterone that would be necessary to accelerate the growth of a cancer of the prostate over and above that which he produces himself? [413]

A. Well, I am still balled up.

Q. Let's look at it this way—

A. I think what you are trying to say is, if the individual produces testosterone and you give him some more, will that light up the cancer. I think it will.

Q. How much more is necessary?

A. Nobody can say. It may be a very small amount or a very large amount. Dr. Huggins is taking a small island of growth which he had de-

(Testimony of Elmer Belt, M.D.)

tected of the prostate in the early stages of his work back in 1940, and probably that he could detect an increase in the size of that growth by giving testosterone and a decrease by giving stilbestrol, and he could alternate it and make it get larger or smaller. The same thing could be done using very small quantities of testosterone to increase the amount of acid phosphatase in the blood in an individual whose acid phosphatase level was a little high. If he gave just a small quantity of testosterone, the acid phosphatase would rise rapidly. If he gave stilbestrol, the acid phosphatase would drop and he could use that as an indicator of the spread of the growth.

Q. That would be after the cancer was a recognizable and a diagnosable cancer, wouldn't it?

A. Yes.

Q. I am talking about an incipient cancer. Say the man produced a certain amount of testosterone. Is that measurable? [414]

A. We only can measure it in amount as a discard.

Q. Do you consider that would be an accurate measure as to the amount that he produces?

A. No; it probably isn't but it is the only way we have of doing it.

Q. Then, let us say that that man takes a very small quantity of methyl testosterone. How are you able to say with certainty and not mere opinion that the growth of that cancer was accelerated

(Testimony of Elmer Belt, M.D.)

simply by what was given to him rather than by what he produced, or some other factor?

A. In those experiments that I have described, which Dr. Huggins performed, that was the only added factor, in the two cases which I described for you a few days ago. The added testosterone, in one case being methyl testosterone and in the other case being testosterone propionate, was the only unusual factor which could be called into account for a very unusual clinical phenomena. We are not magicians. We deal only with the materials we have at hand and the observations we can make. But, when you introduce one factor only which produces the very bizarre clinical phenomena, you are inclined to believe that that factor is the cause of the bizarre phenomena.

Q. Dr. Warren Nelson, who testified here the other day, talked about the subject of sterility and the effect of [415] testosterone on a person's sterility. He spoke about the damage to the testes that would occur under certain circumstances from its administration. He mentioned in his testimony, if counsel will pardon me for not going to the record for it—I couldn't put my finger right on it—that, in order to determine the amount of damage that had been done to the testes from the administration of testosterone, it would be necessary to take a biopsy and take a portion of the tissue of the testes and examine it microscopically. In your practice do you perform biopsies on a man's testicles to deter-

(Testimony of Elmer Belt, M.D.)

mine whether or not testosterone is making him sterile?

A. No; we don't. We perform biopsies on testicles for other purposes but not for that.

Q. Do you know of any doctors who perform biopsies on a man's testicles for the purpose of determining whether or not the testosterone that he has been taking is making him sterile?

A. There is so much simpler method that I wouldn't think they would perform biopsies. One might wish to have that as the ultimate but, when we want to know whether the patient's sperm count is dropping, we have him masturbate and examine the specimen.

Mr. Neukom: Just a minute. I think you had better refer to the testimony of Dr. Nelson.

Mr. Elson: All right. Let's get the record. It is on [416] page 100. If I misquoted Dr. Nelson, I didn't mean to. This was his testimony after speaking about the administration of testosterone, page 99, line 2, "Q. How could it, then, be determined whether or not there had been any damage to the testosterone-producing portions of the testes? A. The only way one can ascertain that is by examination of the testes and looking at the interstitial cells, noticing the atrophic changes that have been promoted by the inhibiting influences of the administered testosterone.

"Q. Is that the microscopic examination of a slide of a portion of the testes——

A. Yes, sir.

Q. ——Under a slide?

A. Yes, sir.

(Testimony of Elmer Belt, M.D.)

Q. (By the Court): Just how do you get at that? How do you examine the testes under a slide?

A. A small piece of the testes is removed.

Q. (By the Court): By surgical operation?

A. By surgical operation, usually under a very simple local anesthetic. The tissue is properly fixed and sectioned and stained, the usual pathological procedure.

Q. (By the Court): How would that be called for except by just some experiment? That does not seem like a practical thing. Who would have that done?

A. It is being done very, very widely, now."

Q. Has that been your experience?

A. You are speaking now of a different thing than you spoke of there. When you brought up that subject, without reading the record, you spoke of the spermatogenic property [417] of the testicle—

Q. Wait a minute, Doctor. Let's not get into that. I wasn't talking about that at all. I was confining it simply to the broad question of sterility and the effect of testosterone upon a person, tending to make a man sterile.

A. Surely, but he is not talking about that there. What he is talking about is the testosterone-producing proclivity.

Q. Let me ask you this. Isn't it material to know whether a person is becoming sterile or not, by the use of testosterone—to know whether or not the testes are producing testosterone?

A. No. They are two different functions entirely of the testicle. The testicle produces spermatozoa

(Testimony of Elmer Belt, M. D.)

and the spermatozoa are the things which fertilize the female.

Q. But the testes in the interstitial cell also produce testosterone?

A. That is right. And testosterone is not an essential to the insemination of the female.

Q. Whether we do—— A. Now——

Q. Wait just a minute. Whether we do this for the purpose of determining whether the testosterone is making a man sterile or anything else, has it been your experience that the operation that Dr. Nelson refers to is done very, [418] very widely now?

A. For what he refers to, it is done widely.

Q. What is that?

A. That is to determine whether or not the endocrine part of the testicle is at fault.

Q. Do you mean experimentally or in actual practice?

A. In practice one can determine whether the testicular mechanism is below par in its activity or not by direct examination of the interstitial cells. It is not difficult to perform.

Q. If a man is not producing any sperm cells, he at least is infertile or becoming so?

A. If he is not producing any, he would be sterile.

Q. And, if the number of sperm cells that he is producing is not sufficient to reproduce, he has at least become infertile, hasn't he?

A. That is right.

Q. Is it your understanding of what Dr. Nelson

(Testimony of Elmer Belt, M. D.)

was talking about that that was an examination to determine whether or not the amount of the spermatozoa in the testes was sufficient or whether or not the man was becoming infertile?

A. No. Those are two different departments of thought. In one case it is a matter of the production of testosterone. In the other case it is a matter of the production of spermatozoa. [419] They are done by two wholly different things inside of the testicle. They are tested for differently to determine the number of spermatozoa and their activity and their form, and you simply have the patient bring you a post-coital specimen or have him ejaculate a specimen in the office by masturbation and examine it and that shows you this data. You are speaking of the department of fertility. A man can be totally infertile with azoospermia. An example of that is that of mumps of the testicle. Mumps orchitis will produce a complete azoospermia.

Q. Meaning what? A. No sperm.

Q. If he has no sperm, he can't produce, can he?

A. He can have sexual intercourse but he cannot reproduce.

Q. Let's get back to Dr. Nelson again. I am going back to page 98, line 5, "Q. (By Mr. Danielson): Can you make an opinion on the basis of your professional training, experience, education, your studies of the literature and the results of your conferences and discussions with other scientists and doctors, as to the effect of administered methyl testosterone on the testes?

"A. Yes. For instance, methyl testosterone has

(Testimony of Elmer Belt, M. D.)

quantitatively the same effect as testosterone, the effect on the testes is the same. [420]

“Q. What would that effect be?

“A. The inhibition of sperm cell production and the inhibition of the production of testosterone by the interstitial cells.

“Q. Would potency as such be a valid indication of whether the interstitial cells producing testosterone are or are not functioning under those conditions?

“A. No, because the administered testosterone would, of course, provide the necessary chemical agent for the induction of potency, in other words, the administered testosterone would take the place of the individual's own testosterone, which is no longer being produced in the same amount as before treatment.

“Q. How could it, then, be determined whether or not there had been any damage to the testosterone-producing portions of the testes?

“A. The only way one can ascertain that is by examination of the testes and looking at the interstitial cells, noticing the atrophic changes that have been promoted by the inhibiting influences of the administered testosterone.

“Q. Is that the microscopic examination of a slide of a portion of the testes——” and then we went on.

Then, let's get down to page 99, line 21——

A. So far that is all very clear and logical.

Q. Just a minute. “Q. (By the Court): How

(Testimony of Elmer Belt, M. D.)

would that [421] be called for except by just some experiment? That does not seem like a practical thing. Who would have that done? A. It is being done very, very widely now. Q. It is? A. In cases of infertility or sterility or suspected disease or abnormal function of the testes. It is a widely recognized procedure at the present time."

A. Yes, sir.

Q. In actual practice?

A. In actual practice.

Q. Do you mean to say, Doctor, that, if a man has been taking testosterone and if the doctor suspects that maybe he is becoming sterile or infertile, that it is widely accepted practice for the doctor to take a biopsy of a portion of the man's testes and find that out?

A. No. You are reading a lot of things into Dr. Nelson's statement that he didn't make.

Mr. Danielson: I object to that as not being based on the facts quoted by Mr. Elson.

Mr. Elson: I don't think I am misquoting it.

A. No. You are just not understanding it, what Dr. Nelson says.

Q. Wait a minute——

A. Let me tell you——

Q. Wait a minute. Let me ask the questions first and then you tell me. Let's come right back to what he said on [422] page 100, where he said that it was widely done now. He said, "In cases of infertility or sterility or suspected disease or ab-

(Testimony of Elmer Belt, M. D.)

normal function of the testes. It is a widely recognized procedure at the present time.”

A. Now, stop. He makes no reference to testosterone administered for any purpose then. He states that in infertility and in hypogonadism this is a widely recognized procedure and carried out.

Q. Let's go back to what he says. Let's go back to page 99, a question by Mr. Danielson as to whether, as a result, and so on, of his experience, he can testify or can state his opinion as to the effect of administered methyl testosterone. Then he goes on, on page 98 and on 99, which I will read, “Q. How could it, then, be determined whether or not there had been any damage to the testosterone-producing portions of the testes? A. The only way one can ascertain that is by examination of the testes and looking at the interstitial cells, noticing the atrophic changes that have been promoted by the inhibiting influences of the administered testosterone.” What we are talking about is whether there had been any damage to the testosterone-producing portions of the testes by the administration of testosterone. “A. The only way one can ascertain that is by examination of the testes and looking at the interstitial cells, noticing the atrophic changes that have been promoted by the inhibiting [423] influences of the administered testosterone. Q. Is that the microscopic examination of a slide of a portion of the testes— A. Yes, sir— Q. Under a slide? A. Yes, sir. Q. (By the Court): Just how do you get at that? How do you examine the testes under a slide? A. A

(Testimony of Elmer Belt, M. D.)

small piece of the testes is removed. Q. (By the Court): By surgical operation? A. By surgical operation, usually under a very simple local anesthetic. The tissue is properly fixed and sectioned and stained, the usual pathological procedure. Q. (By the Court): How would that be called for except by just some experiment? That does not seem like a practical thing. Who would have that done? A. It is being done very, very widely now."

A. Right there he departs from the thought of testosterone.

Q. Just a moment. "Q. It is? A. In cases of infertility or of sterility or suspected disease or abnormal function of the testes. It is a widely recognized procedure at the present time."

A. Yes; that is right. For instance, if you walk down the street, you don't always walk down the street to your bank to get money. So you are separating the walking—— [424]

* * *

Q. (By Mr. Elson): Let's leave Dr. Nelson. As Mr. Danielson said, I think we can let the record speak for itself. In your direct testimony the other day, at page 249, line 16, the following questions and the following answers were given, "Q. Are there any subjective symptoms of this male hormone deficiency which a layman could recognize and accurately use to diagnose such condition?

"A. Oh, gosh, I wouldn't think a layman could know. He might confuse almost anything with loss of what he thought was his normal quantity of

(Testimony of Elmer Belt, M. D.)

hormones. If he just began to feel tired and run down or if his tennis arm was not satisfactory, or if he made too many strokes in his game of golf, he might decide that he was passing into the climacteric and therefore should take a few testosterone linguets.

“Q. Doctor, in your experience, has such been the case?

“A. Oh, yes. We are taking people off of this stuff all the time.

“Q. And what, as the result of your studies, has caused them to start using this preparation?

“A. They read in the newspapers they must. We have a gullible American public.”

The Court: Which witness was it said that?

Mr. Elson: Dr. Belt.

Q. Do you know of Dr. Morris Fishbein?

A. Yes; I know him personally.

Q. And who is he, for the record?

A. He is a doctor of medicine who is licensed to practice in the State of Illinois and has his office in Chicago.

Q. Dr. Fishbein occupies some office with the American Medical Association, doesn't he?

A. Yes. I am not sure just what it is. I think he is secretary of the American Medical Association.

The Court: Executive secretary?

A. Executive secretary; yes.

Q. (By Mr. Elson): Dr. Fishbein, so far as you know, has a large part to do in guiding, at least up to recently, certain of the activities and policies of

(Testimony of Elmer Belt, M. D.)

the American Medical Association, or speaking for it? A. Yes; he has been doing that.

Q. And isn't it true, in your opinion, that the average well-informed layman knows who Dr. Fishbein is and associates him with the American Medical Association? A. I am afraid he does.

Q. Do you know whether or not Dr. Fishbien compiles certain medical information for the Cosmopolitan Magazine, under the portion which is called "New in Medicine"?

A. I believe he does write such a column. [426]

Q. I call your attention to the April, 1949, issue of the Cosmopolitan Magazine, under that heading, purporting to be compiled by Dr. Fishbein, and I call your attention to a short paragraph under "Testosterone and Fatigue." I will read it for the purpose of the record and then ask the question. "Experimental studies, by physiologic methods of frogs' muscles proved that animals injected with the male sex hormone, testosterone, had 10 per cent greater resistance to fatigue than ordinary animals. Administration of the male sex hormone before the study, increased the capacity to do more work by approximately 51 per cent. Furthermore, the male sex hormone reduced the rate of muscle fatigue during repeated periods of work." [427]

* * *

Q. Considering who Dr. Fishbein is, who he is considered to be by the average well-informed American, and an article such as that, would that statement, appearing in the Cosmopolitan Magazine,

(Testimony of Elmer Belt, M. D.)

would you consider a reader of that article to be gullible if he took that and inferred from it that testosterone might have the same effect upon him as it did upon the frog mentioned by Dr. Fishbein?

Mr. Danielson: Your Honor, I object to that as being incompetent, irrelevant and immaterial, improper cross-examination and argumentative.

The Court: I will sustain that.

A. It is a lot of fun anyway.

Mr. Elson: I was taking the statement of the witness about the gullibility of the American public.

Mr. Danielson: We will stipulate to that.

The Court: The court can take judicial notice of that. [428]

* * *

The Court: Before this passes out of my mind, I would like to ask the doctor a few questions. In your knowledge and observation of the cases you mentioned, where testosterone was administered for a certain kidney ailment and for a disorientation of certain patients and for sores that would not heal on the lower limbs, I am desirous to know if the administering of the drug in those cases, over a considerable period of time and a considerable quantity of the drug—if there was any observation of record as to whether that had in any manner promoted any cancerous or stimulated any cancerous condition in the prostate of the male concerned or in the breast of the female concerned.

A. No, we have never seen it do that, but we have always examined these patients carefully first

(Testimony of Elmer Belt, M. D.)

to be sure [429] that we haven't any evidence of the existence of malignant cells or cells that are suspicious of being malignant, before we begin that type of therapy, and in that I am speaking of the group of elderly men you had referred to. But in the other case, these young people are usually below the age of 45 and there is less danger of causing that kind of trouble in persons under 45 years of age. In fact, I believe there have been no observations that tend to show that cancer would be enhanced in individuals of that age because they don't have the little groups of cells that initiate the growth.

The Court: Counsel may proceed.

Mr. Elson: I don't think I will take very much longer.

Q. By the way, do you know who Dr. Elmer L. Sevringhaus is? A. No.

Q. To refresh your mind, isn't he the director of medical research for the Roche-Organon Company?

A. My goodness, I wouldn't know that.

Q. Do you know of a book called The Modern Home Medical Adviser?

A. Is that by Dr. Morris Fishbein?

Q. Yes; edited by him.

A. I have never seen it.

Q. There is a chapter in this book entitled "Endocrinology" by Elmer L. Sevringhaus—his identity is not [430] material—commencing on page 550, the subject being "The Testes or Male Sex Glands," which are discussed. I don't think that it is necessary to read the whole thing in the record. The

(Testimony of Elmer Belt, M. D.)

portion that I have in mind is only one sentence, the last sentence in the paragraph, at the top of page 551. It reads, "In summary, it may be said that testosterone is the hormone which is required to stimulate development from boyhood to manhood, and to maintain typically manly qualities thereafter." [431]

In your opinion, would a layman be considered gullible who read that and believed that testosterone or the male sex hormone product would maintain typically manly qualities after he had reached manhood? A. No; he wouldn't.

Q. If I told you, Doctor, and I will shortcut this and I think counsel will not object to it—if I told you that in this book, which is obviously for consumption of the layman, there is no reference to testosterone, possibly, probably or otherwise encouraging or affecting or accelerating the growth of a cancer of the prostate, don't you think that the average person reading that would, therefore, eliminate or it would never enter his mind that testosterone would have anything to do with such acceleration?

A. If that was his only source of knowledge and he depended upon that wholly for everything he knew, he probably would be allowed to come to that conclusion.

Q. You haven't seen this book, have you?

A. No; I haven't seen it before.

Mr. Elson: I might say that the book is edited by Morris Fishbein, M. D., your Honor, the gentle-

(Testimony of Elmer Belt, M. D.)

man whom Dr. Belt has described, and on the title page it says, "Modern Home Medical Adviser for Health and How to Preserve It, Edited by Morris Fishbein, M. D."

A. Home doctor books are as old as the world.

The Court: I should like to ask you, Dr. Belt, if that book or any publication, which seems to have the editorship of a man of the standing of Dr. Fishbein, if it extols the virtues of a drug for the purpose mentioned and it is silent as to any of its dangers from the effects of the use of the drug, would you regard that as a dangerous publication?

A. In that way it is, of course. I have never seen that book but I am sure you will find statements throughout which repeat often that a layman should not self-administer drugs. I am certain that Dr. Fishbein would not produce a book of that sort without giving that warning.

* * *

Mr. Elson: I only have one or two other questions.

Q. Doctor, do you think that a man who is in middle age or life and who complains of these various symptoms, such as flushes, sweats and so on, as was enumerated, without repeating them, that the question of his sterility or fertility [433] is important at his age compared to his desire to be relieved of those symptoms?

A. So many things crowd into my mind as a result of that question that I will say it is difficult

(Testimony of Elmer Belt, M. D.)

to separate them into an understandable flow of thought, but I will try to. Whatever a man is beset with at the moment is an important thing to him. If he has hot flushes and feels tired and weary and all that, it is a very important thing to him at that moment. But in the long view, it may be of much greater importance to that man to maintain his fertility.

Q. Why?

A. Suppose a man is 40 years of age and he has three children and he has a wife, and the three children and the wife go merrily down the road in the new automobile that he has bought for them, and they are all killed. The day before their death he thought he would never have another child. But a few months later, he marries again and marries a young woman and then the matter of propagation is of importance.

Q. Don't you think that is a far-fetched analogy?

A. Not when there were over 600 people killed over this Fourth.

Q. Well, take a man 40 years old. Is that a far-fetched analogy?

A. No. You are wrong there. You should practice medicine and see the number of people who change their wives at 45. [434]

Q. (By Mr. Elson): Isn't it true that there are a lot of men who have vasectomies performed?

A. Well, they try to have in males. We discourage it pretty much.

(Testimony of Elmer Belt, M. D.)

Q. Well, vasectomy, explain to the court what it is.

A. Vasectomy is a method of severing the duct between the testicle and the seminal vesicle in order to produce sterility through blocking the flow of sperm into the seminal vesicles and preventing the female partner from being inseminated and fertilized.

The Court: That can be restored, though, by another operation, can it not?

The Witness: Your Honor, the possibility of restoring it is remote. I have tried it in about 15 cases. I have only seen one patient who had babies afterward. We have seen spermatozoa appear in the ejaculation afterward, but these patients apparently don't fertilize their partners because the spermatozoa seem to appear in too small numbers, and that is the general experience with that operation. After the vas has been occluded for a long period of time, the sperm count in the restored ejaculated sperms seems invariably to be low.

Q. (By Mr. Elson): Do you feel that before testosterone should be prescribed to a person, that the doctor ought to warn that it may cause him to be sterile? [435]

A. A young person I think should be, yes.

Mr. Elson: I think that is all.

(Testimony of Elmer Belt, M. D.)

Redirect Examination

By Mr. Danielson:

Q. What do you mean by azoospermia? Is that the same as sterility?

A. Azoospermia means that there are no spermatozoa. "A" is the Greek derivative.

Q. Azoospermia would produce sterility, then?

A. Yes.

Q. Do you perform the acid alkaline phosphatase test in your urology group? A. Yes.

Q. That is a procedure which you follow from time to time, is that correct? A. Yes.

Q. Doctor, a good deal was asked as to what would a general practitioner do under the circumstances comparable to the so-called male menopause. A. Yes.

Q. Now, you mentioned the precautionary examinations which were given. Assume for a moment, Doctor, that the patient told you that he was referred by another doctor who gave him such drugs from time to time, would that change the procedure at all?

A. Well, if a patient comes to me referred by another [436] physician, I always allow the other physician the benefit of whatever doubt that might exist in my mind and my tendency is to go on with the original treatment he has established until I can communicate with him and discuss the problem with him. It is possible that the patient may not tell me things that he has communicated to his other physi-

(Testimony of Elmer Belt, M. D.)

cian. It is possible that I may not see things in that patient that the other physician saw. So, in the first place, a generously disposed human being would not say right away, "Oh, your doctor is doing the wrong thing. By goodness, this is the trouble." But you would conform to the treatment until you had an opportunity for discussion and coming to a common understanding of that.

Q. That is what I had in mind. Now, would counsel object to my reading a small paragraph from one of these articles?

Mr. Elson: No.

Mr. Danielson: This is a reprint from the Northwest Medicine, of Seattle, Volume 46, No. 12, page 949, December, 1947. The article is entitled "Present Status of Male Hormone Therapy." From the second page I quote:

"Caution: Male hormone is contra-indicated, if there be any suspicion of cancer of the prostate, and had better be avoided in cases of arteriosclerosis, hypertension and cardiac disease." [437]

Q. Doctor, as to that one particular phrase, do you have any dispute? A. No.

Mr. Danielson: No further questions.

Recross-Examination

By Mr. Elson:

Q. In other words, Doctor, as to that particular

A. Oh, well, you must understand that we all have our hobbies and a hobby is something that

(Testimony of Elmer Belt, M. D.)

makes a man bend over backward in one direction. It is a slant——

Mr. Elson: Well, I think I was being a little facetious. I have no further questions. [438]

* * *

Mr. Neukom: It will be stipulated, will it not, Mr. Elson, that a document similar to Government's Exhibit 14-A, the pamphlet, was passed out and was available to whosoever might be interested?

Mr. Elson: That is correct.

Mr. Neukom: In addition to that, at the time in question [441] and prior to the dates in question, there was run in local newspapers of general circulation various advertisements advertising these hormone products by the defendant here. Is that correct?

Mr. Elson: Correct.

Mr. Neukom: Without offering those, your Honor, we will merely enter into a stipulation that from time to time the local newspapers offered for sale male and female hormones, without the necessity of a prescription. I mean the local newspapers printed the advertisements.

Mr. Elson: That is correct. [442]

* * *

Mr. Danielson: If your Honor please, the government is prepared at this time to stipulate that the transactions reflected in the first nine counts, counts 1 through 9, inclusive, of the information, involve sales and shipments to government agents,

agents who communicated with the defendant and made the purchases which were subsequently made with the drugs being sold to these government agents and shipped to the government agents. This was done in the regular course of business, however.

Mr. Elson: That is right.

The Court: The allegations from what?

Mr. Danielson: 1 through 9.

Mr. Elson: Counts 1 to 9, inclusive.

Mr. Danielson: That is correct.

The Court: 1 through 9.

Mr. Danielson: These transactions were between the defendant and government agents, in the regular course of business.

* * *

The Court: Now, the government rests?

Mr. Danielson: The government rests, your Honor.

Mr. Elson: When I did it before, maybe it was premature, [445] but at least for the record I make a motion for a judgment of acquittal in the case of United States of America vs. El-O-Pathic Pharmacy, Inc., et al., No. 20596 Criminal, and I also make a motion for a judgment of acquittal in the case of United States of America vs. Allen H. Parkinson, No. 20642 Criminal.

The Court: I will hear you on the motions.

Mr. Elson: Well, your Honor, I will be very, very frank. I think that Mr. Sturzenacker concurs with me that I am making that motion for the purpose of protecting my record and I did not intend

to and, frankly, am not prepared at the present time to argue extensively any such motion.

The Court: The motion is denied.

The Clerk: Your Honor, is that in both cases?

The Court: In both cases, yes. They were made at the same time. [446]

* * *

The Court: In the El-O-Pathic case let the ruling be considered in accordance with that, then.

Mr. Elson: And then I withdraw my motion as to the Parkinson case.

The Court: And the ruling of the court in the Parkinson case is withdrawn?

The Court: Yes, because there is nothing before the court—no motion before the court. [448]

* * *

MARTIN A. CLEMENS

one of the defendants herein, called as a witness on behalf of the defendants, being first duly sworn, testified as follows:

Direct Examination

The Clerk: Your full name? [455]

The Witness: Martin A. Clemens.

Q. (By Mr. Elson): Mr. Clemens, what is your connection with the El-O-Pathic Pharmacy, Inc., a corporation?

A. I own the stock in the company.

Q. And you are the manager and director of the corporation?

A. That is correct.

(Testimony of Martin A. Clemens.)

Q. Do you also operate the M. A. Clemens Pharmacy? A. I do.

Q. Now, are you a pharmacist?

A. Yes, sir.

Q. Admitted to practice pharmacy in this state?

A. Yes, sir.

Q. How long have you been? A. 1927.

Q. Now, you sell, do you not, testosterone?

A. I do.

Q. And, in other words, the other products that are mentioned in the information? A. I do.

Q. Now, at least in the fall of 1947, from whom were you buying those products?

A. From the Roche-Organon Company, Ciba Pharmaceutical Supply, from the Schering Corporation.

Q. In connection with the products that you purchased [456] from them, did you also receive literature from those companies?

A. Yes, sir, we did.

Q. And you have seen the literature, some of it that has been introduced or used in the course of this trial so far? A. I have.

Q. Was that similar to the literature that you received at least from those companies?

A. It was.

Q. Now, in connection with this pamphlet, "Male and Female Sex Hormones," an exhibit in this case, what was the source of the information contained in that pamphlet?

(Testimony of Martin A. Clemens.)

A. It was paragraphs taken from the manufacturers' pamphlets.

Q. One manufacturer or several?

A. All of them.

Q. How long have you been selling testosterone?

A. Since 1943.

Q. Has anyone, at any time, made any complaint concerning the alleged damage or injury from the use of the product to you?

A. They have not.

Q. Are you able to tell us approximately how much testosterone you have sold since 1943? [457]

A. In boxes, or in amount of pills?

Q. In boxes?

A. Approximately 127,000 boxes. [458]

The Court: Were they all the same size?

A. They were different sizes.

The Court: It doesn't seem to mean much, then, unless there is an average as to the quantity. 127,000 boxes varying in size doesn't convey much meaning to the court.

Mr. Elson: Let's try and do it this way.

Q. Approximately how many tablets have you sold since 1943?

A. Between four and five million tablets.

Q. And how are those tablets sold; in what sized boxes?

A. Well, originally they were sold in boxes of 15, 30s and 100s and later on the manufacturer changed them to 30s and 100s and 500s.

Q. Can you give us an estimate of about the

(Testimony of Martin A. Clemens.)

percentage of business that comprised the 15 tablets to a box?

A. That was a small percentage. I don't remember the exact amount.

Q. I show you here a paper, on the letterhead of the El-O-Pathic Pharmacy, and ask you if you recognize the handwriting.

A. That is my handwriting.

Q. How long ago did you prepare that?

A. In the past 10 days.

Q. After having looked at that, is your memory refreshed as to the approximate percentage of your business [459] that comprised sales of 15 to a box?

A. It is.

Q. How many? A. 20 per cent.

Q. And approximately what percentage of your business comprised the boxes of 30 tablets to a box?

A. 30 to 50 tablets; 70 per cent.

Q. And what percentage of your business comprised the sale of tablets of a hundred to a box?

A. About 10 per cent.

The Court: You didn't mention the 500.

Q. (By Mr. Elson): Did you say 500?

A. We very rarely sell 500s. It is usually used for dispensing in smaller bottles.

Q. In other words, it is a negligible quantity?

A. That is right.

Mr. Elson: Does that answer your Honor?

Q. Did you carry Products Liability Insurance?

A. We did.

Q. That is, do you carry it now?

(Testimony of Martin A. Clemens.)

A. We do.

Q. How long have you carried it?

A. Approximately five years.

Q. With one company or several?

A. The past three years it has been with one company. [460]

Q. And who is that?

A. The United States Fidelity and Guaranty Company of Baltimore, Maryland.

Q. Do you remember who you were insured with for that purpose prior to that time?

A. No; I don't.

Q. What is the amount of insurance that you carry?

Mr. Neukom: I will object, your Honor. It is not material.

Mr. Elson: I will withdraw it.

Q. Now, Mr. Clemens, in Counts 5, 7 and 9, it is alleged that you sent to the persons referred to in those counts, on the dates mentioned in those counts, testosterone. It is not alleged that there was any accompanying literature with those shipments, such as is referred to in the other counts, and by that I mean the pamphlet "Male and Female Sex Hormone." Do you get that? A. No; I don't.

Q. In Counts 5, 7 and 9 of the information, it is alleged that you shipped testosterone or mailed it to the individuals referred to in those separate counts and that you mailed that to them on the dates that are referred to in each of those counts. It is not alleged, however, that with those shipments

(Testimony of Martin A. Clemens.)

went the pamphlet here, "Male and Female Sex Hormone"; in other words, that it didn't accompany it at all. [461] Do you get me now?

A. Yes, sir.

Q. Do you remember whether or not with those particular shipments referred to in those counts—do you have any independent recollection of having shipped one of these pamphlets here and—well, go ahead and answer.

A. One or two pamphlets went out with every shipment.

Q. Was that your usual and customary practice?

A. Yes, sir.

Q. Was it infrequent or invariable?

A. Always.

The Court: As a part of the shipment or under separate cover?

A. A pamphlet went out with every shipment.

The Court: That is, right along with the package? A. Yes, sir.

The Court: In the same package?

A. Yes, sir.

Q. (By Mr. Elson): In Count 10 the allegation is made that you shipped a box with the labeling "Female" on it. Do you remember that?

A. Yes, sir.

Q. I will show you a photostatic copy of the governments exhibit here and it is alleged that you sent this alpha estradiol in that package, with that scratched out and [462] with the word "Female"

(Testimony of Martin A. Clemens.)

written on there. Do you remember that particular transaction? A. I don't.

Q. What was your practice with regard to sending out estradiol or female hormones, in so far as any literature was concerned on the female hormones?

A. We used the manufacturer's literature to accompany the product. If it was Schering, we would use Schering's literature, or, if it was Roche-Organon, we would use Roche-Organon literature.

Q. On the female you sent manufacturer's literature? A. That is correct.

Q. I show you here a brochure of Roche-Organon, having to do with oral estrogen therapy, and ask you if you have seen that before.

A. I have.

Q. Is that the manufacturer's literature to which you referred? A. Yes, sir; it is.

Mr. Elson: May I offer this in evidence, please?

Q. Was it infrequent or your invariable practice to send such brochures with such product?

A. The brochures went out with every order.

Mr. Elson: We will offer this as the defendants' next exhibit. [463]

The Clerk: That will be Defendants' Exhibit C in evidence.

(The document referred to was marked Defendants' Exhibit C and received in evidence.)

Q. (By Mr. Elson): On some of these shipments did you take out of the original package in

(Testimony of Martin A. Clemens.)

which it came cellophane packages containing tablets of testosterone? A. We did.

Q. After having taken those out, did you send those to persons who ordered them?

A. We did.

Q. These tablets came in what form?

A. They came in boxes of a hundred tablets, 20 strips to the box.

Q. By "strips" do you mean they were in cellophane strips? A. That is correct.

Q. Similar in appearance to this one I am holding in my hand now? A. Exactly.

Q. And, when a person ordered say five tablets or ten tablets, or we will say less than the number contained in the original package, how did you fill the order?

A. We reboxed them and put a circular in with them.

Q. What do you mean by reboxed them? [464]

A. We put them in a separate mailing box.

Q. Do you mean the strips? A. Yes.

Q. And mailed them with the circular?

A. With the circular.

The Court: Was it this circular or was it another one?

A. It was the male hormone circular.

Q. (By Mr. Elson): I show you here a circular or brochure—counsel has stated that they don't have any objection to my speaking to the witness a minute.

(Testimony of Martin A. Clemens.)

(Inaudible conversation between Mr. Elson and the witness.)

Q. Now, in Count 5 it is alleged that you removed five tablets from an original package that you received from Roche-Organon and shipped that or you mailed it to somebody in some other State. I can't remember now who it is. Do you recall that?

A. That is right.

Q. I show you here a brochure entitled "Oral Androgenic Therapy, Roche-Organon." Have you seen those before?

A. Yes, sir; I have.

Q. Now, what was your practice with reference to products received from Roche-Organon in which you removed say five or ten tablets and sent those by mail?

A. We sent a circular along with it. [465]

Q. Such as this one here?

A. Yes, sir.

Mr. Elson: I offer this as the defendant's next exhibit.

The Clerk: That will be Defendants' Exhibit D in evidence.

(The document referred to was marked Defendants' Exhibit D and received in evidence.)

Q. (By Mr. Elson): Did you receive similar brochures from the other two companies, Ciba and Schering?

A. We did.

Q. That described the use of the product and so on?

A. Yes, sir.

(Testimony of Martin A. Clemens.)

Q. Was your practice the same in connection with taking out five or ten tablets, of Schering or Ciba, which you mailed to somebody in another State? A. It was.

Q. You mailed the brochure that was Schering's—if it was Schering's tablets, you mailed their brochure along with them?

A. Yes, sir; that is correct.

Q. And the same would be true of Ciba's?

A. Yes, sir.

The Court: You mailed a copy of this circular or one that you had printed yourself, which?

A. We mailed that circular. [466]

The Court: This one?

A. Yes, sir.

Q. (By Mr. Elson): You received considerable quantities of such circulars from the manufacturers? A. We did.

Q. When I say considerable quantities, about how much did you receive from them?

A. As many as we needed.

Q. Would it go into the hundreds or thousands?

A. Thousands.

Q. In Count 2 the charge is that you shipped certain Menformon Dosules, a product of Roche-Organon Company, to a person in Phoenix, Arizona. Those dosules are an ointment, are they not?

A. That is correct.

Q. For the purpose of being rubbed on a woman's breast? A. That is correct.

(Testimony of Martin A. Clemens.)

Q. You purchased those from Roche-Organon?

A. We did, sir.

Q. In Count 3 it is alleged that you sent those dosules to John R. Winch in Phoenix, Arizona. Did you send those in the original package in which they were received by you from the manufacturer?

A. Yes, sir.

Q. In connection with that product, did you—or was [467] there any accompanying brochure or literature that went with it?

A. Yes, sir; there was.

Q. I show you here defendants' exhibit I guess it is. Is that the product that went with it?

A. Yes, sir; it was.

Q. Or I mean brochure.

A. Yes, sir; it was.

Q. And that was the brochure that you received from Roche-Organon?

A. Yes, sir.

Q. Now, I show you here two invoices, one dated December 3, 1947, and the other one dated September 18, 1947. Keeping in mind the date of shipment in Count 3, December 28, 1947, was the product that you shipped under Count 3, on December 28, included within the merchandise covered by either of those invoices?

A. Yes, sir; it was.

Q. Which one would it be, if you know?

A. The one that is dated December 3, 1947.

Mr. Elson: I offer that invoice into evidence.

* * *

The Clerk: Defendants' Exhibit E in evidence.

(Testimony of Martin A. Clemens.)

(The document referred to was received in evidence and marked Defendants' Exhibit E.)

The Court: May I ask the witness a question now?

Q. In this Male Sex Hormone Androgenic Therapy, there is a statement to the effect that if X-ray examination discloses evidence of increased bone age, that the use of the drug should be discontinued. What does bone age mean?

A. Oh, that is a medical term, your Honor.

Q. (By Mr. Elson): Have you ever yourself used testosterone?

A. I have. [474]

Q. For how long?

A. The past two years.

Q. And in what size doses?

A. A hundred milligrams weekly by injection, and from 25 to 50 milligrams daily, to supplement it.

Q. Injections by a doctor?

A. Yes, sir.

Q. After having taken this product, describe how you felt.

A. Well, it gave me a lift, it gave me a sense of well-being, it kept me from being loggy.

Q. In other words, you felt better?

A. Felt better.

Q. So far as you know, you suffered no ill effects?

A. None whatsoever.

The Court: How long did you say you took it?

A. The past two years.

The Court: Regularly all this time?

(Testimony of Martin A. Clemens.)

A. Yes, sir.

The Court: Two years. You started out with that dose and continued it right along?

A. I started out with 25 milligram doses and then, when the manufacturer increased the strength of the product to the same—well, they used to manufacture 25 cc's to the injection and now they manufacture 50 to each injection and I [475] increased the doses at the time.

The Court: You doubled it?

A. Yes, sir, your Honor.

The Court: And took it daily, hypodermically?

A. No. Once a week. Daily, orally, by sublingual.

* * *

Q. (By Mr. Elson): Mr. Clemens, have you gone to other drug stores in the State of California and purchased testosterone? A. I have.

Q. In what form? A. Tablets.

Q. Linguets or tablets?

A. Tablets and linguet form.

Q. Where have you done that?

A. Up and down the state.

Q. Well, explain what you mean, please?

A. On a trip to San Francisco, I stopped at every town I got a chance to and if they had four drug stores I would go into two of them and make a buy. I had no difficulty.

Q. You purchased it over the counter?

A. Yes. [476]

Q. Have you made any such purchases in the city of Los Angeles? A. I have.

(Testimony of Martin A. Clemens.)

Q. Recently? A. Yes, sir.

Q. Where?

A. Oh, practically any store.

Q. Well, let us put it this way: At many drug stores or only a few? A. Many.

Q. By many what do you mean?

A. Well, I would say nine out of ten.

Mr. Elson: Cross-examine.

Cross-Examination

By Mr. Danielson:

Q. How old are you, Mr. Clemens?

A. 42.

Q. Have you ever been convicted of a felony, Mr. Clemens? A. No, sir.

Q. Never? A. No, sir.

Q. Now, Mr. Clemens, you have mentioned that in all of your sales of the hormones you transmitted various circulars or circulars at least with these shipments, is that correct? [477]

A. That is correct.

Q. And that was true of this little pamphlet, "Male and Female Sex Hormones," the little pamphlet of your own, is that not correct?

The Court: What was the answer?

Q. (By Mr. Danielson) (Continuing): I am referring specifically, Mr. Clemens, to what appears as Government's Exhibit 2-A and comparable circulars.

The Witness: Now, what is the question, sir?

(Testimony of Martin A. Clemens.)

Q. (By Mr. Danielson): You transmitted these circulars with your shipments, likewise, is that correct? A. Yes, sir.

Q. And that is true of all of these shipments and transactions which are reflected in this information, is that not correct? A. That is correct.

Q. Now, Mr. Clemens, I direct your attention to a transaction of November 1, 1947, which is the subject of the first count of this information alleging the shipment of a package of male hormones to John R. Winch of Phoenix, Arizona. Do you remember that particular transaction?

A. Yes, sir.

Q. Do you remember what was the labeling you transmitted with that particular shipment?

A. What was on the label? [478]

Q. What circulars or pamphlets, literature, did you transmit with that shipment?

A. If it was a male hormone, we sent them the literature from the male hormone leaflet.

Q. You sent them this pamphlet "Male and Female Sex Hormones," is that not correct?

A. Yes, sir.

Q. And did you send any other literature?

A. Manufacturers' literature.

Q. You are sure of that? A. Yes, sir.

Q. You remember that particular incident, is that correct, this particular transaction?

A. I do not remember that particular transaction, but one of them went into every package. I inspect every order that goes out.

(Testimony of Martin A. Clemens.)

Q. But you do not remember that particular transaction, do you? A. No, sir.

Q. All you know is that there was such a shipment? A. That is right.

Q. Now, I invite your attention to what is known as count 2 of this information. It involves a sale, a shipment on or about October 30, 1947, to John R. Winch, Phoenix, Arizona, again of a package of tablets containing 25 milligrams [479] of testosterone each. Do you remember that particular shipment?

A. No, I don't remember that particular shipment.

Q. Do you know what labeling went out with it, what circulars and literature?

A. If it was a male hormone, a male hormone circular went with it.

Q. Both your own pamphlet, the "Male and Female and Sex Hormones," and you say some manufacturers' literature went with it?

A. That is right.

Q. Now, Mr. Clemens, I invite your attention to what is count 3 of this information, which is based on a shipment of Menformon Dosules to John R. Winch of Phoenix, Arizona. Do you remember that particular shipment? A. I do.

Q. You do? A. Yes, sir.

Q. And what literature accompanied that shipment?

A. Manufacturers' literature with the description of the bust development.

(Testimony of Martin A. Clemens.)

Q. And what else? A. And our pamphlet.

Q. And now you are referring to this "Male and Female Sex Hormones" pamphlet? [480]

A. That is correct.

Q. Now, Mr. Clemens, as to count 4 of this information which is based on a transaction on or about November 18, 1947, and a shipment to Robert C. Brandenburg—rather, a sale to Robert C. Brandenburg, do you remember that particular transaction? A. No, sir.

Q. Do you know what literature accompanied that transfer of hormones, 25 milligrams testosterone?

A. Testosterone—manufacturers of testosterone literature and our own.

Q. You are certain of that? A. Yes.

Q. Now then on count 5 of the information we have a transaction, five tablets of 25 milligrams testosterone sold to Robert C. Brandenburg on or about November 18, 1947. Do you remember that particular transaction? A. No, sir.

Q. Do you know what literature would have accompanied it?

A. The literature of the manufacturer.

Q. Plus your own? A. Plus our own.

Q. —pamphlet, the "Male and Female Sex Hormones"? A. That is correct. [481]

Q. And to count 6 of the information charging that on or about October 27, 1947, a quantity of five tablets of 25 milligrams testosterone was sold to one

(Testimony of Martin A. Clemens.)

Allen T. Spiher, Jr. Do you remember that transaction? A. Would you repeat that, please?

Q. Allen T. Spiher, Jr., a sale of 5 tablets containing 25 milligrams of testosterone each.

A. Was that a shipment?

Q. It was on or about October 27, 1947. These tablets were placed into an envelope and sold and disposed of to Allen T. Spiher on the surrender of nothing but money, in payment therefor. Do you remember that transaction?

A. That was an over-the-counter sale?

Q. Apparently it was. A. Yes, sir.

Q. Do you remember what literature accompanied that sale? A. No, I don't.

Q. You don't remember on that. Would that transaction have been different from the other transactions we have just covered?

A. It would.

Q. Why would that be?

A. I knew he was a federal drug inspector.

Q. And you don't know what literature it accompanied, [482] however? A. No, sir.

Q. I take it that you know Mr. Spiher, is that correct? A. That is correct.

Q. Now, in count 7 of the information, it alleges specifically that on or about October 27, 1947, a sale again of five tablets of 25 milligrams testosterone, again to Allen T. Spiher, Jr. Do you remember that transaction? A. I do.

Q. Do you remember what literature accompanied it? A. No, sir.

(Testimony of Martin A. Clemens.)

Q. And in count 8?

A. Was that an over-the-counter sale?

Q. Apparently it was.

A. Or was that a shipment? Then, the answer is the same.

Q. And in count 8 of the information, on or about November 20, 1947, a sale again of five tablets of 25 milligrams testosterone to one Allen T. Spiher, do you remember that transaction?

A. I do.

Q. And do you remember what literature accompanied it? A. I do not.

Q. And in count 9 of this information, a transaction on or about November 20, 1947, a sale of five tablets containing [483] 25 milligrams each of testosterone to one Allen T. Spiher. This apparently is over-the-counter likewise. Do you remember that transaction? A. I do.

Q. And do you remember what literature accompanied it? A. I do not.

Q. Now, directing your attention again, Mr. Clemens, to the transaction involving the sale of Menformon Dosules, I believe you have testified that the information contained in your little blue pamphlet, your Male and Female Sex Hormones pamphlet, was lifted from the literature of some manufacturer, is that correct? A. That is correct.

Q. Is the literature in your own pamphlet substantially that which appeared in this manufacturer's pamphlet? A. That is correct, sir.

Q. Without any material changes in it?

(Testimony of Martin A. Clemens.)

A. That is right.

Q. How did you copy it from there? You yourself decided what portions to reincorporate in your own, is that not right?

A. It is just cut out of the original pamphlet and pasted onto a sheet.

Q. You read it before you did that, did you not?

A. Yes, sir. [484]

Q. Then, you noticed the full text of the manufacturer's pamphlet, including the citation of some authority? Is that not correct?

A. I do not have the pamphlet here in front of me.

Mr. Danielson: Do you have Defendant's Exhibit A here?

The Clerk: Yes.

Q. (By Mr. Danielson): Mr. Clemens, I will invite your attention to Defendants' Exhibit A which purports to be a little brochure relative to Menformon Dosules, particularly to the bottom of page 2. Now, I ask you, Mr. Clemens, is that the portion that you incorporated in your little pamphlet of "Male and Female Sex Hormones"?

A. I do not remember. I do not have a pamphlet here.

Q. It is right there.

(Mr. Danielson indicates exhibit to the witness.)

A. This paragraph was taken from this pamphlet right here (indicating).

(Testimony of Martin A. Clemens.)

Q. When you say "this paragraph," identify what document you are talking about.

A. The last paragraph on the circular of our own.

Q. That is on the bottom of what would be page 4, the back sheet, am I not correct?

A. That is correct, and it was taken from——

Q. Defendants' Exhibit A?

A. Defendants' Exhibit A. [485]

Q. (By the Court): It has a subheading, "Results from male hormones," is that right?

Mr. Danielson: No, your Honor. On the bottom of page 4 of the little blue pamphlet, the reverse page, the back page, under the heading "Breast Development." That was lifted from the second paragraph on the second page of Defendants' Exhibit A, is that correct? A. That is correct.

* * *

Q. (By Mr. Danielson): Now, Mr. Clemens, I should like to point out to you that in the manufacturer's brochure, in referring to these hormones, does he not cite various authority such as C. M. McBride, J.A.M.A. 1932, 112:1045, that is cited in Defendants' Exhibit A, is that not correct, the manufacturers' literature? A. That is correct.

Q. And it is not cited, however, in your personal literature, is it? A. No, sir.

Q. But, nevertheless, in reading it—you edited that [486] out, you eliminated that yourself, is that not correct? A. That is correct.

(Testimony of Martin A. Clemens.)

Q. Now, you testified, did you not, that these manufacturers would supply you with all the literature you wanted, that is, any quantity of literature that you would want? A. That is correct.

Q. Up to several hundred thousand copies, if need be, is that correct? A. That is correct.

Q. That is likewise true of Roche-Organon, is that not correct? A. That is correct. [487]

* * *

Q. (By Mr. Danielson): Why did you find it desirable, Mr. Clemens to lift out this portion from the manufacturer's brochure and put it in your own?

A. You mean why I decided to omit that one sentence?

Q. No. Why did you find it necessary to reprint the manufacturers' brochures when they would supply you with all the copies you wanted?

A. They quit supplying them.

Q. I thought you said they would supply you with all the copies you wanted.

A. They did, for a while.

Q. As a matter of fact, wasn't it more convenient to omit those portions which referred to the medical literature?

A. No. That wasn't correct.

Q. Now, as to all this literature which accompanied these transactions, Mr. Clemens, you remember that in the instances other than those involving Mr. Spilher, do you remember, are you sure that the other literature went along with those, the manu-

(Testimony of Martin A. Clemens.)

facturers' literature accompanied those transactions? A. Yes, sir.

Q. As a matter of fact, isn't it true that it is a rather convenient afterthought, two years afterwards, to remember that some other literature accompanied them?

A. No, sir. We always had a policy to put one or more circulars in every package, and they were always checked. [488]

Q. Now, you have testified that you sold around four to five million tablets of methyl testosterone since you have been in this particular business, is that not correct? A. Yes, sir. [489]

* * *

Q. (By Mr. Danielson): In addition to the literature to which I have called your attention, did Roche-Organon or Ciba or any of these other companies supply you with literature in addition to this little brochure?

A. Do you mean the manufacturers' brochures?

Q. That is right; in addition to Defendants' Exhibit A, and I believe there are two others, probably D and E.

A. The Schering Corporation supplied us with other literature.

Q. How about Roche-Organon?

A. Roche-Organon only supplied us with literature pertaining to the product we were buying from them.

Q. I would like to invite your attention, Mr.

(Testimony of Martin A. Clemens.)

Clemens,—could this be marked for identification, please?

The Clerk: Government's Exhibit No. 18 for identification.

(The document referred to was marked Government's Exhibit No. 18 for identification.)

Q. (By Mr. Danielson): I would like to show you this document, Mr. Clemens, which purports to be a letter from Roche-Organon, and ask you if you have ever seen it before. A. I have.

Q. You received one of those from Roche-Organon, is that correct? A. That is correct.

Q. Did you read that, Mr. Clemens?

A. I did.

Q. Did it not make restrictions, Mr. Clemens, on the use to which you could put this literature which they distributed?

A. At that particular time, they did.

Q. And that was in July, 1947?

A. That is right.

Q. And what were those restrictions?

A. They told us not to give out too many of them.

Q. As a matter of fact, didn't they make it more strong than that?

A. They might have in the letter but they kept supplying us anyhow.

Q. I would like to invite your attention here to a phrase, "This pamphlet has been prepared for

(Testimony of Martin A. Clemens.)

dissemination to the medical profession exclusively." Do you remember such a statement?

A. That is right.

Q. Here is another, "All Roche-Organon products, with the exception of cytora, are strictly prescription items; literature, therefore, must be kept out of the hands of your customers. You would be breaking faith with your physicians to do otherwise. In fact, you might even endanger lives, for hormones are powerful therapeutic agents which must be administered [491] under strict medical supervision." You remember that, do you not?

A. I remember that; yes, sir.

Q. That was put out by the manufacturer of that drug, was it not? A. That is correct.

Q. And do you remember they also told you, "So pass along these facts to all your clerks: (1) Roche-Organon literature is for physicians only. (2) Keep Roche-Organon literature out of reach of your customers. (3) All Roche-Organon products (except cytora) bear an Rx legend on their labels, and therefore, may be dispensed only on a physician's prescription. (4) Don't give out literature with prescriptions for Roche-Organon products even when the patient asks for it"? Do you remember that?

A. I remember that in the letter but that is not what their agents told us to do.

Q. But you do remember this letter, do you not?

A. Yes, sir.

(Testimony of Martin A. Clemens.)

Q. You mentioned Ciba, did you not, that Ciba has put out some literature? A. Yes, sir.

Q. Are you familiar with this literature that Ciba puts out along with their hormonal products?

A. Some of it. [492]

* * *

Mr. Danielson: Your Honor, I should like to offer Government's Exhibit 18 for identification in evidence.

The Clerk: Government's Exhibit 18 in evidence.

(The document referred to was marked Government's Exhibit No. 18 and received in evidence.)

* * *

Q. I want to direct your attention, Mr. Clemens, to some other literature put out by Ciba. You have seen their little booklet entitled "Male Hormone Therapy," have you not, from Ciba's?

A. Yes, sir.

Q. And you have looked it over, have you not?

A. Yes, sir.

Q. Do you remember their statement, and I am quoting from page 146, "The use of androgens and the treatment of other conditions such as cryptorchidism, the 'male climacteric,' angina pectoris, ovarian dysfunction (functional uterine bleeding), dysmenorrhea and other gynecologic conditions is experimental and cannot be recognized until more conclusive evidence becomes available"?

And, again on the same page, "The male sex

(Testimony of Martin A. Clemens.)

hormone is contraindicated in the following conditions:

Sterility: Large doses may cause azoospermia since the hormone secreted by it tends to inhibit the gland which produces it."

And, again, "Carcinoma of the prostate: It is unwise to give testosterone propionate in these cases."

The Court: What carcinoma was that?

Mr. Danielson: Of the prostate.

Q. You have seen the literature put out by Ciba, "A summary of sterility sex hormone therapy," no doubt? A. Yes, sir.

Q. Did you notice on page 13 thereof contraindications, "Androgens are contraindicated——"

Mr. Elson: Just a moment. What is the date of that book? [494]

* * *

Mr. Danielson: The pamphlet from which I am about to quote is dated 1947 and, moreover, Mr. Clemens has stated he is familiar with it. I should like to question him about it.

The Court: He didn't admit that he was familiar with it at the time that these transactions involve.

Q. (By Mr. Danielson): Mr. Clemens, is it not true that this literature put out by the manufacturer is the type of literature you have been describing and with which we are now [495] dealing, distributed by the manufacturers through outlets from time to time in the course of their business transactions? A. That is correct.

(Testimony of Martin A. Clemens.)

Q. And, in 1947, you received the 1947 information and, likewise, in 1948, you received the 1948 information, is that correct?

A. We received them; yes. [496]

Q. Inviting your attention to this booklet with which you have mentioned you are familiar, "Steroid Sex Hormone Therapy," you did have occasion to see this, is that not correct?

A. Just recently; yes.

Q. It was made available to you, however, a couple of years ago? A. That is right.

Q. And you are in the business of selling these hormones, are you not? A. That is right.

Q. In fact, you obtained the wording for your own literature from these various pieces of literature distributed by the manufacturer, did you not?

A. That is correct.

Q. Did you not take the trouble to notice that, on page 13 of this little pamphlet, with the heading "Contraindications——"

Mr. Elson: Wait just a minute, Mr. Danielson. You haven't shown yet that he read this, even though it might have been in 1947, prior to the time that any of these shipments were made.

Mr. Danielson: If your Honor please, it has been established, in the first place, that the defendant is familiar with the pamphlet; in the second place, that it was published [497] in 1947; third, it was received by him about that time, and, fourth, it was available and could have been read by him.

Mr. Elson: Whether he did or not is a question of fact.

(Testimony of Martin A. Clemens.)

The Court: I haven't heard any evidence that he received it in 1947.

Q. (By Mr. Danielson): I believe you testified, did you not, that you received this a couple of years ago? A. I believe I did.

Q. Well, did you?

A. I don't remember that book but, offhand, I have not gone through all of these booklets. I don't know when I received them. They shipped them to us but I don't remember the dates.

Q. You don't remember when you went through them for sure, then?

A. That is right. It is only recently I have been reading those booklets.

Q. Why have you started reading them recently?

A. Because of the government charges here.

Q. Have you changed that little pamphlet, "Male and Female Sex Hormones" recently?

A. I don't remember when I saw it last.

Q. Why did you not include, Mr. Clemens, those things, the statement relative to carcinoma and the statement relative [498] to sterility? Why did you not include those in your little pamphlet?

Mr. Elson: Just a minute. He says he doesn't recall having recently changed them.

Mr. Danielson: He has referred to Defendants' Exhibit A. That is one which I am confident Mr. Clemens recalls. The other pamphlets which have been mentioned—Mr. Clemens has testified he did receive this literature and did look at this pamphlet on Male Hormone Therapy.

(Testimony of Martin A. Clemens.)

The Witness: That deals with testosterone propionate and we don't have much to do with that.

Q. (By Mr. Danielson): How about androgens? Do they include methyl testosterone?

A. Yes; they include methyl testosterone.

Q. The statement so far as it applies to androgens would cover methyl testosterone?

A. That is correct.

Q. But you published no warnings as to the use of them, is that correct? A. No, sir.

Q. Now, you stated a while ago that you have been taking these hormones for some time. Do you take them under the supervision of a physician?

A. No, sir.

Q. How did you say you received this injection?

A. By a doctor.

Q. That has been going on for a year or two?

A. That is correct.

Q. And the doctor is still administering it, is that right? A. That is right.

Q. How come you consulted a doctor, Mr. Clemens?

A. I had no way of injecting it myself.

Q. You didn't ask the doctor for any device, then, I gather? A. No, sir.

Q. You told him what to do and he did it?

A. That is correct.

Q. He conducted no examinations at any time?

A. None whatsoever.

Q. And then you have no way of knowing whether you have any early or incipient carcinoma of the prostate, do you? A. No, sir.

(Testimony of Martin A. Clemens.)

Q. How did you get started taking these hormones, Mr. Clemens?

A. I just wanted to check to see what they would do.

The Court: Did you find out that they had the potency to do the things that the manufacturers suggested?

The Witness: Yes, sir; they do. [500]

Q. (By Mr. Danielson): Now, Mr. Clemens, you mentioned that you buy these hormones at nine out of ten drug stores without a prescription.

A. That is correct.

Q. Did you ever try Horton & Converse's?

A. Yes.

Q. Did you succeed?

A. Well, I can buy it there; yes.

Q. You happen to be a pharmacist, do you not?

A. That is right.

Q. Do you know whether a lay person can?

A. I wouldn't know.

Q. Have you tried it out at the Rexall Drug Stores downtown? A. Some of them.

Q. Some of them turned you down?

A. That is right. I don't give my credentials or anything.

Q. Can you name any one pharmacy down here that has sold you the hormones without knowing you are a pharmacist and [501] without a prescription? A. Any one pharmacy where?

Q. Downtown in Los Angeles.

(Testimony of Martin A. Clemens.)

A. Oh, sure; yes, sir. The one on the corner of Fourth and Broadway, two doors north, and there is one in the middle of the block between Fifth and Fourth on Broadway, and there is one on the corner of Fourth and Broadway.

Q. What is this store at Fourth and Broadway now?

A. It is a little store——

Q. Is it a Rexall store?

A. No, sir. This is a regular drug store.

Q. What is the name of this drug store?

A. I don't recall the name. It is about three or four doors north of Fifth and Broadway, on the eastside of the street.

* * *

Q. Would you be more particular in telling us what this drug store is?

A. It is a little drug store about four doors north of Fourth and Broadway, on the east side of the street. [502]

Q. Fourth and Broadway or Fifth and Broadway?

A. Fifth and Broadway.

Q. Do you know of any other reputable drug store downtown?

Mr. Elson: What do you mean by "reputable"?

The Witness: A drug store on the corner of Fifth and Spring, the Alexandria Drug Company, and a drug store on the corner of Fourth and Broadway, the Safety Drug Company.

Q. (By Mr. Danielson): And at those drug stores you can buy methyl testosterone without a

(Testimony of Martin A. Clemens.)

prescription and without being a pharmacist?

A. That is correct. [503]

* * *

Cross-Examination

(Resumed)

By Mr. Danielson:

Q. Mr. Clemens, when you were on the stand yesterday, I believe you did testify, did you not, that you are a pharmacist?

A. That is correct.

Q. You are licensed to practice your profession here in California? A. Yes, sir.

Q. Where did you go to school to study your profession? [505]

A. I didn't go to school to study it.

Q. But you did pass the State Board, or whatever it is called? A. That is correct.

Q. In your preparation as a pharmacist, you learned, of course, that a pharmacist deals with the public in his trade at all times, did you not?

A. Yes, sir.

Q. And that the pharmacist, by virtue of his type of business, has to deal with not only more or less innocuous remedies but, likewise, poisons, dangerous remedies and a wide quality of products, is that correct? A. That is correct.

Q. And that a pharmacist, in dealing with the public, has a duty at least not to wilfully deceive the public in its contacts, relative to these subjects, is that correct? A. That is correct.

(Testimony of Martin A. Clemens.)

Q. And I imagine wilfully not to deceive—or you might say in good practice you would use good faith and confidence in dealing with the public, isn't that correct? A. That is correct.

Q. And you have been practicing pharmacy since about 1937, is that correct? A. 1927.

Q. And I presume that you, likewise, have not wilfully [506] deceived the public in your business, is that not correct? A. That is right.

Q. You have used good faith and confidence in all of your dealings with the public?

A. That is correct.

Q. And I presume that was true when you were in your hormone business, is that correct? You didn't wilfully deceive the public in the hormone business? A. No, sir.

Q. That was true at the time of the counts alleged in this information, in 1947 and 1948? You were still using good faith and confidence in your dealings with the public? A. Yes, sir.

Q. You were not wilfully deceiving the public?

A. No, sir.

Q. In this literature you passed out, that little pamphlet "Male and Female Sex Hormones," which is identified as Exhibit 1-A in the exhibits, and also several other exhibits, you didn't wilfully deceive the public there, did you? A. No, sir.

Q. And I presume that is true of all of your literature that you passed out, of any representa-

(Testimony of Martin A. Clemens.)

tions made to the public? You didn't wilfully deceive the public then? A. No, sir. [507]

Q. And you don't deceive the public today, for that matter, do you? A. No, sir.

Q. You still use good faith and good business during any dealing with the public?

A. Yes, sir.

Q. In all of your representations?

A. Yes, sir.

Q. Mr. Clemens, since you have been using good faith and confidence, I don't imagine you would object, would you, to having the court see some of the ads you put out to the public?

A. No objection. [508]

* * *

Mr. Danielson: For the record, I should like to have these marked for identification. I have a photostat of page 34 of the Los Angeles Daily News, dated October 15, 1947.

The Clerk: That will be Government's Exhibit No. 21 for identification.

Mr. Danielson: I have page 30 of the Los Angeles Times, Sunday, April 17, 1949.

The Clerk: That will be Government's Exhibit No. 22 for identification.

Mr. Danielson: And page 22, Part One of the Los Angeles Times for Wednesday, June 8, 1949.

The Clerk: Government's Exhibit No. 23 for identification. [510]

Mr. Danielson: And page 8-B, Los Angeles Daily News, Tuesday, July 5, 1949.

(Testimony of Martin A. Clemens.)

The Clerk: Government's Exhibit No. 24 for identification.

Q. (By Mr. Danielson): Now, Mr. Clemens, I invite your attention to Government's Exhibit No. 21 for identification, particularly to an ad in the right-hand column just above the middle of the page, relative to hormones, M. A. Clemens, Pharmacist. That is one of the ads that you caused to be published, is it not? A. That is correct.

Q. And you are aware, naturally, of the contents of that ad, isn't that correct?

A. That is true.

Q. Likewise, I invite your attention to Government's Exhibit No. 22 for identification, the lower right-hand portion of the page, an ad relative to male hormones, with the address of El-O-Pathic Pharmacy. That is one of your ads, is it not?

A. That is correct.

Q. And you are familiar with the contents of that ad? A. Yes, sir.

Q. And, likewise, in Government's Exhibit No. 23 for identification, in the lower left-hand portion of the page, another ad of the El-O-Pathic Pharmacy. Is that one of your [511] ads, Mr. Clemens?

A. That is correct.

Q. And you are, of course, familiar with the contents of that, are you not? A. Yes, sir.

Q. Then, again, on Government's Exhibit 24 for identification, a newspaper of July 5, 1949, I direct your attention to an ad at the lower left-hand por-

(Testimony of Martin A. Clemens.)

tion of the page. That is from El-O-Pathic Pharmacy. It is one of your ads, too, is it not?

A. That is correct.

Q. And you are aware of the contents of it?

A. Yes, sir; that is right.

Q. Now, Mr. Clemens, in publishing these ads, both those of recent date and the one back there in 1947, you were, again, you say, using good faith and confidence and were not misleading the public, is that not correct?

A. That is correct. [512]

* * *

Q. (By Mr. Danielson): You testified yesterday, Mr. Clemens, that you have studied a booklet, "Summary of Steroid Sex Hormone Therapy," which was likewise published by Ciba?

A. I don't believe I said I studied it.

Q. You read it?

A. I glanced through it.

Q. Copyright, 1947. On page 13 of which is a statement to the effect:

"Contraindications," stating, "Androgens are contraindicated under the following circumstances:

"1. In the presence of carcinoma of the prostate particularly and carcinoma in general."

And a little further down, on page 13:

"Caution should be exercised in administering androgens over long periods to individuals with normal testicular function, since androgens have been reported as inhibiting [516] spermatogenesis."

You did read that, did you not?

(Testimony of Martin A. Clemens.)

Mr. Elson: Just a minute. Is that going to the question of credibility, Mr. Danielson?

Mr. Danielson: To a large part, yes.

Mr. Elson: Well, I submit that the question is objectionable on the grounds that I have already stated.

Mr. Danielson: It goes not only to the credibility, it does go to credibility, but likewise to one of our principal allegations, and that is that there is misbranding in this case because of false and misleading statements in the literature.

The Court: Objection overruled. The witness may answer.

The Witness: What is the question?

(Question read as follows: "You did read that, did you not?")

Mr. Danielson: I believe the witness has testified, yesterday, that he did, is that not correct?

A. That is correct.' [517]

* * *

Q. Very well. Now, Mr. Clemens, is it not a fact that in using good faith and confidence in dealing with the public, you would not wilfully mislead them as to any danger in these products of which you were aware?

A. No, I wouldn't. I checked all these dangers before I——

* * *

Mr. Danielson: Now, Mr. Clemens, you had no reason at the time of the publishing of these ads

(Testimony of Martin A. Clemens.)

and of the pamphlet, "Male and Female [518] Sex Hormones," which is Government's Exhibit 1-A and other numbers, you had no reason to believe that there was any danger involved in the use of these products, is that correct, of the male or female sex hormones?

A. I believe there was none. I checked with the state authorities but they gave me no reason to believe that there was.

Q. You had no reason to believe? A. No.

Q. And you apparently still have no reason to believe, is that correct? A. That is right.

Q. Now, Mr. Clemens, did you not formerly do business as Clark's Drugs and Sundries, Clark's Drugs or Clark's? A. Yes, sir.

Q. And likewise as M. A. Clemens?

A. That is right.

Q. Isn't it a fact that as far back as October 23, 1947, the fact of danger in these products was forcibly brought to your attention by the Federal Trade Commission?

A. I don't believe they brought the fact of danger. It was advertising the—it was the advertising they were interested in.

Q. And what was the nature of that warning? Wasn't it an order to cease and desist? [519]

A. That is correct.

Q. And what was the basis of that warning?

A. In what way?

Mr. Elson: Let me see it. [520]

(Testimony of Martin A. Clemens.)

Q. Now, Mr. Clemens, having received this, did you [524] subsequently issue this literature which by this very letter was restricted to physicians?

Mr. Elson: Just a minute. I object to that question on the grounds that counsel is placing a construction on the letter itself, which is something which this court can determine. If you will confine your question to did he subsequently put out this literature, I have no objection to it.

Mr. Danielson: I have no objection to phrasing that question in that manner, frankly, Mr. Elson.

Q. Did you? Having received this letter, did you subsequently put out the literature referred to in it?

A. They told me to ignore that letter.

Q. Well, did you? A. Yes.

Q. Why did you?

A. The manufacturers' managers told me to ignore that letter, that was merely put out to appease the medical profession, and they kept supplying us with that literature from then on.

Q. You mean to say that the agents of Roche-Organon issued this letter and then came around and told you to disregard it?

A. Not the agents. That came from the company's offices in Nutley, New Jersey. The local agents here told me to ignore the letter and they kept supplying me with literature as [525] long as they had it.

Q. That is, you mean contact men for this company?

(Testimony of Martin A. Clemens.)

A. The general managers of this company, yes.

Q. Told you to ignore it?

A. Yes. They put this letter out so that it would have that action on the medical profession, and they told me not to pay any attention to it.

Q. (By Mr. Danielson): What was the purpose of the letter, then?

Mr. Elson: Wait a minute. I object to the question. What was the purpose of the letter, that is asking for a bald conclusion on the part of the witness.

Q. (By Mr. Danielson): Well, what did they tell you was the purpose of the letter?

Mr. Elson: What did who tell him?

Mr. Danielson: These contact men of Roche-Organon.

A. They had to keep their product council-accepted with the medical profession, that they still had to have the outlet counceled.

Q. In other words, this was just sort of a front to make it all sound very legitimate, is that correct?

A. Well, I don't know what opinion you have of it.

Q. That was the net effect of it, was it not?

A. They told me to continue passing out and selling the product. [526]

* * *

Q. (By Mr. Danielson): Well, having received this letter, you nevertheless did issue the literature?

A. Yes, I did. I was told to ignore the letter.

(Testimony of Martin A. Clemens.)

Q. Even though the letter says to do so would be breaking faith with the physicians, is that not correct? [527]

* * *

Q. (By Mr. Danielson): Did you issue these products back at this time, 1947 and 1948, with or without a prescription, Mr. Clemens?

A. Without.

Q. And that is true today, I presume, is that not correct? A. That is correct.

Q. Mr. Clemens, directing your attention now to the product Menformon Dosule, that is Roche-Organon product? A. That is right.

Q. I show you a photostatic copy of Government's Exhibit 3-A which purports to be a package of Menformon Dosules. A. That is correct.

Q. You are familiar with this label, I presume?

A. Yes, sir.

Q. You are likewise familiar with the paragraph, "Caution: To be dispensed only by or on the prescription of a physician"? A. Yes, sir.

Q. And that label has been carried on the package, was carried on the package during 1947 and '48, was it not, Mr. [528] Clemens?

A. Yes, sir.

Q. But you sold without a prescription, nevertheless? A. That is correct.

Q. There is one more thing, Mr. Clemens: Mr. Clemens, yesterday I asked you a question——

Mr. Neukom: While he is looking for that, I would like to offer in evidence newspaper advertise-

(Testimony of Martin A. Clemens.)

ments. We at one time offered them and then we withdrew them, and they are Exhibits 21, 22 and 23.

Mr. Elson: I am going to object to them on the same grounds I objected to them before. [529]

* * *

The Court: The ruling on the admissibility of the report of the State Board, which was offered yesterday, is set aside in view of the present offer. The report of the State Board of Pharmacy will be admitted. As to these advertisements, I don't care to go much further with a matter that is in its nature, in large part advertising but I will go this far with the report that you offered, Mr. Elson, and these four newspapers——

Mr. Elson: In view of that, I will withdraw my objection to the newspaper articles for the purpose stated by Mr. Neukom.

Mr. Neukom: Very well.

The Clerk: Those are Government's Exhibits 21, 22, 23, and 24 in evidence. [531]

* * *

Q. (By Mr. Danielson): Mr. Clemens, yesterday I asked you, at page 477 of the transcript, "Q. Have you ever been convicted of a felony, Mr. Clemens?" "A. No, sir.

"Q. Never? A. No, sir."

Now, Mr. Clemens, it is possible that there is a mistake here but are you not the M. A. Clemens who appeared before Judge Leon Yankwich of the United States District Court here in Los Angeles, on April 12, 1937? A. That is correct.

(Testimony of Martin A. Clemens.)

Q. And what was the nature of that charge? Was it not the selling of a compound containing a derivative of opium, to wit, morphine, in a preparation known as Pine Cherry and Guaiacol Compound—

A. That is a cold remedy.

Q. —in violation of Title 26, Section 1044, of the United States Code? [532]

A. That is right.

Q. And the result of that was a conviction, was it not?

A. It was a fine on a misdemeanor charge. We discussed it with the Judge.

Mr. Danielson: The section of the code, 1044-A, I believe the court will take judicial notice of, is a felony.

The Witness: It was reduced. We talked that over with the Judge. There were maybe two or three hundred druggists up there at one time. There was some technicality of whether the syrup could be sold or not. Thrifty, Sontag and several others, all of them, were convicted and the Judge ruled it was a misdemeanor and find us \$200.

Mr. Danielson: Very well. As I mentioned, on that there could possibly be a mistake.

No other questions. [533]

* * *

Mr. Elson: I have no other questions of Mr. Clemens.

The Court: May I ask you, did you acquire these

(Testimony of Martin A. Clemens.)

drugs in question by direct purchase from the manufacturers and shipment from them directed to you or did you purchase them through some sales agency, from a supply kept by such agent or agents here?

The Witness: We purchased them direct from the manufacturer. Some of the time the manufacturer would ship them out to their agents and they, in turn, would deliver them to us but always we paid directly to the manufacturer.

The Court: And you ordered them directly from the manufacturer?

The Witness: Yes, sir.

The Court: Did each of these three concerns from whom you bought these goods have local sales agencies?

The Witness: Yes, sir; and daily contact. [534]

* * *

Mr. Elson: Dr. Fakehany, please.

GEORGE E. FAKEHANY, M.D.

called as a witness for the defendants, being first duly sworn, testified as follows:

The Clerk: Your full name, Doctor?

The Witness: George E. Fakehany (spelling same), M.D. [535]

* * *

Direct Examination

By Mr. Elson:

Q. Dr. Fakehany, you hold a degree of Doctor of Medicine, do you? A. I do.

(Testimony of George E. Fakehany, M.D.)

Q. Where did you attend school?

A. Loyola University, Chicago.

Q. Did you graduate from there?

A. I did.

Q. In what year? A. 1937.

Q. Did you receive any honorary degree with your M.D. degree? A. I graduated cum laude.

Q. In medicine? A. Yes, sir.

Q. Did you intern at any hospital?

A. I did.

Q. Where?

A. Los Angeles General Hospital.

Q. For how long?

A. A two-year period.

Q. Were you a resident physician at any hospital for any period of time? A. I was.

Q. What hospital was that? [536]

A. The Good Samaritan Hospital.

Q. Here in Los Angeles? A. Yes, sir.

Q. In what year? A. In 1939.

Q. And you took the State Board in California in what year? A. 1938.

Q. And passed it at that time? A. I did.

Q. Are you admitted to practice medicine in any other State than California? A. I am.

Q. What State? A. Ohio.

Q. Are you a member of any medical associations?

A. I am a member of the Los Angeles County Medical Association and the Hollywood Academy of Medicine.

(Testimony of George E. Fakehany, M.D.)

Q. Are you engaged in general practice?

A. I am.

Q. In your practice, are you a medical consultant or examiner for any large companies?

A. I am.

Q. Will you state for what companies?

A. I am the medical examiner for Technicolor Motion [537] Picture Corporation, a large Hollywood manufacturing concern, and Samuel Goldwyn Studios and RCA.

Q. That is the Radio Corporation of America?

A. Of America. I think those are the largest.

Q. In this case there has been charged that methyl testosterone in tablet form, among other things, 25 milligrams to be taken one to two tablets daily, is dangerous in that that product of that dosage may accelerate the growth of an incipient carcinoma of the prostate and may cause sterility. Now, keeping that in mind, in your opinion, would it be possible for you to diagnose or discover an incipient carcinoma of the prostate?

A. Incipient carcinoma of the prostate gland represents the very beginning of a prostatic carcinoma, and it is most difficult at this time to diagnose carcinoma of the prostate gland.

Q. About how large would the carcinoma of the prostate have to be before you would be able to feel it by palpation?

A. It would have to be at least the size of a grape or acorn.

Q. Why is that?

(Testimony of George E. Fakehany, M.D.)

A. If it was any smaller, it would be lost in the substances of the prostate gland. In the very beginning, it is impossible to differentiate the cells from the normal prostatic tissue. [538]

Q. Is the prostate gland surrounded by a covering of any kind?

A. It has a thick capsule.

Q. Does that have any effect on your ability to feel it by palpation?

A. In examination of the prostate gland, particularly through the rectum, it must necessarily be made through the thick capsule surrounding the prostate gland and you try to determine what is within the capsule.

Q. Have you in your practice ever used a blood or a urine test to detect an incipient cancer?

A. I never have.

Q. Do you know of any practitioners in general practice who do that?

A. Ordinarily, doctors in general practice do not use this type of examination.

Q. What examinations are there, besides palpation, with which you are familiar, and that are commonly used by doctors in this locality in detecting an incipient carcinoma of the prostate, other than by palpation?

A. There are none that I know of.

Q. Have you read the literature from time to time concerning the relationship of the use of testosterone to prostatic cancer?

A. I have. [539]

(Testimony of George E. Fakehany, M.D.)

Q. And what has that literature, in general, consisted of?

A. The literature suggests that methyl testosterone aggravates or might possibly aggravate a carcinoma of the prostate gland.

Q. Is the literature uniform in that suggestion or what?

A. It certainly is not uniform. It is merely suggestive and suggests that you use caution because of the possibility of carcinoma of the prostate. However, there is much confusion in the literature on that subject. [540]

* * *

Q. Doctor, have you ever encountered in your practice a cancer of the prostate? A. I have.

Q. In your practice, approximately how many do you encounter per year, we will say?

A. Well, I would say, on an average, about one every two years.

Q. And you have encountered that by rectal examination?

A. Well, I picked up some by rectal examination but very frequently by X-ray.

Q. In a physical examination?

A. A general physical examination.

Q. Is it possible for you to find a cancer of the prostate?

A. It is if it is far enough advanced.

Q. In your practice, approximately how many physical examinations of men do you estimate that you have given?

(Testimony of George E. Fakehany, M.D.)

A. Well, during the war, I gave thousands of physical examinations. All the large manufacturing plants in Hollywood insisted on physical examinations. I was the doctor that gave them for the Hughes Aircraft Corporation and we did on an average of 20 to 25 physical examinations a day for them.

Q. With all of those examinations, did you find cancer [541] of the prostate frequently or infrequently? A. It is very infrequently found.

* * *

Q. (By Mr. Elson): Before I get to that, I want to lay some more foundation. Have you prescribed in your practice testosterone for people?

A. I have.

Q. How frequently would you say on an average do you prescribe it?

A. I would say on an average of once a day.

Q. In your practice, have you ever encountered any what you considered adverse results as the result of testosterone administration?

A. I never have.

Q. Now, on the basis of what you have read and your experience, do you have an opinion as to whether testosterone will accelerate the growth of an incipient carcinoma of the prostate?

A. I really have no opinion in that respect. I know that there are many doctors that think that it might. Much of the literature suggests that it might and there are many [542] doctors that, frankly, don't know, and I think I am one of them.

(Testimony of George E. Fakehany, M.D.)

Q. But you have never encountered any adverse results from administering testosterone once a day during your practice?

A. I have never had a bad result from it.

Q. As to the subject of sterility, have you read in the literature anything about the subject of sterility in relation to the administration of testosterone? A. I have.

Q. Based upon your experience in the administration of it and what you have read, do you have an opinion as to whether or not the administration of testosterone will cause sterility?

A. I might state that the administration of testosterone will lower the sperm count and for that reason we don't like to give the testosterone over a long period of time to one individual. In other words, we give it for possibly two or three months and then leave them rest a while, due to the fact it does lower the sperm count. But as far as actually producing sterility, I doubt that it does.

Q. In your opinion, do you consider that testosterone is a dangerous drug, based upon your experience?

A. I have had no danger with it at all. I have experienced none. [544]

Q. The usual age of the man to whom you administer testosterone is about what?

A. Between 50 and 65.

Q. Do you consider that the factor of sterility or fertility with a man of that age, who would other-

(Testimony of George E. Fakehany, M.D.)

wise, in your opinion, require testosterone, would be a factor? A. I don't think so.

Q. In the information here it is alleged—or I am going to ask you this. Assuming that a man was suffering from a male sex hormone deficiency, in your opinion, would 25 milligrams of testosterone or 50 per day, methyl testosterone, stimulate the growth—assuming that he has a male sex hormone deficiency, would it stimulate the growth and development of the sex organs?

A. I don't think that it would.

Q. If a man was a hypogonad, do you think testosterone would stimulate his sex organs?

A. It might in that case.

Q. And a hypogonad is a person suffering from a hormone deficiency? A. That is correct.

Q. If a person is suffering from a male sex hormone deficiency, would the administration of testosterone stimulate the growth and development of the male characteristics, such as the distribution of hair, muscular development and depth of [545] voice? A. I think it would.

Q. That is, with the average individual, or are you distinguishing a hypogonad from the average individual?

A. I presumed you were referring to a normal individual.

Q. Let's speak about a hypogonad for a moment. Let's say there is no distribution or a very incomplete distribution of hair, very incomplete muscular development, a lack of depth of voice. Do you think

(Testimony of George E. Fakehany, M.D.)

testosterone would stimulate the growth of those particular elements I have named?

A. It might in an individual——

Q. Let's take an individual who has a normal distribution of hair on his body. If he takes testosterone, it wouldn't make hair grow all over him, would it?

A. Certainly not. [546]

* * *

Q. (By Mr. Elson): What do you give testosterone for?

A. Testosterone is commonly given to a patient that is of the age of anywhere from 45 to 70, that complains of these following symptoms, or a combination of them: Unusual weakness, loss of memory, inability to concentrate, nervousness, general fatigue. He may have any combination of these symptoms. Particularly is it given when there is no evidence of any other pathology, for instance, when there is nothing else you can point the symptoms to. We presume that the individual is suffering from male hormone deficiency or going through the change of life.

Q. In your practice, when a person complains of those symptoms, what do you usually do?

A. Well, I usually talk with him for a few moments to try to determine if there is anything else that bothers him, for instance, if the patient has a bad heart or had had any type of examination or medical care in the past. And, if I can readily determine that the patient doesn't have any organic pathology, I will prescribe or inject male hormones.

(Testimony of George E. Fakehany, M.D.)

Q. And do you give it a try for a certain period of time? A. I do.

Q. Over what period of time do you consider it to be effective for things like that?

A. I usually prescribe about a month's supply and, if [547] the patient is going to get any benefit from it at all, he should come in within that month.

Q. With the great number of people for whom you have prescribed testosterone as you have stated, have you found many of them have been relieved of those symptoms?

A. Many of them and some of them have not.

Q. And, when they have not been relieved, what do you conclude?

A. I conclude that the hormones were ineffective in their particular case.

Q. In other words, that they were not suffering from hormone deficiency? A. Apparently not.

Q. In the practice of medicine, is that an unusual procedure? A. I think it is quite usual.

Q. Is it usual, when a person complains of certain symptoms, for a doctor to conclude that maybe a certain course of treatment will be beneficial and try it and see whether or not it works?

A. It is common practice.

Q. In other words, it is, to a large extent, a method of trial and error, is it not?

A. That is correct. [548]

Q. (By Mr. Elson): Now, for the purpose of determining the efficacy of testosterone, testosterone or let us include estrogens as well, as to their harm-

(Testimony of George E. Fakehany, M.D.)

ful effect, if any, in your opinion, would a large number of tests have to be conducted before it could be considered as proof that harm was to result from the taking of it, or just a few tests, would they suffice? A. I take no tests at all.

Q. No, no, no. I understand that, but I mean from an experimental standpoint, we will say the university. A. Oh, I see.

Q. (Continuing): Or the experimental hospitals, that is what I have reference to.

A. Naturally, the more tests that can be performed to determine whether or not a drug is dangerous, the more the better.

Q. Would you consider that two or three or four tests over a period—wait a minute—that two or three or four instances in which deleterious results to the patient follow the administration of a certain drug would be proof that that drug would in individuals cause damage?

A. You mean two or three or four instances in a country——

Q. Over 15 years.

A. ——in a country of the size of the United States? [549]

Q. Yes. A. I would say certainly not.

Q. In other words, that could be as effective with almost any drug, could it not?

A. I think so, certainly.

Q. Isn't that true with simple home remedies such as, well, let us take aspirin?

(Testimony of George E. Fakehany, M.D.)

A. That might be true of anything, it might be true of common table salt.

Q. Now, then, in his testimony, Dr. Huggins the other day (pages 286 and 287) stated as follows:

“Occasionally we are forced to do things to human beings, in a few cases to make a few observations that are not strictly in the patient’s best interests. We do nothing that will do permanent harm or at least we attempt to, in medical investigation, but we found that the removal of the gonads would cause, in a very spectacular way, widespread cancer of the prostate to shrivel up, to shrink and to disappear.

“Then, we had to try the converse and we gave testosterone to patients with mild cancer of the prostate and when that was done, either 10 milligrams of methyl testosterone a day given by mouth or 5 to 10 milligrams to 25 milligrams of testosterone injected, then the patient became very ill indeed, and had to take to his bed.”

Now, in your practice, is it your practice to experiment [550] with your patients in such fashion?

A. We do not experiment with patients. That is done in laboratories.

* * *

Q. (By Mr. Elson): Doctor, what do you strive for in the treatment of the ailments of your patients or their conditions? [551]

A. Well, we try to get them well, or at least improve their condition.

Q. Now, another thing that Dr. Huggins stated—and you went to school in Chicago, although not the

(Testimony of George E. Fakehany, M.D.)

University of Chicago—at page 294, I believe it was Dr. Huggins who was stating that—oh, I think I will let that go. It is not important enough anyway.

Now, on the subject of impotence, you find impotence in persons on occasions to be psychogenic in origin? A. I do. I certainly do.

Q. Do you find impotence on other occasions to be of some origin other than psychogenic?

A. Yes, sir.

Q. Have you prescribed testosterone for patients who complained of impotence? A. I have.

Q. And have you encountered any good results or adverse results on that subject, afterward?

A. I have had occasion of good results.

Q. The other day, one of these doctors, Dr. Heckel, stated, in answer to a question by the court, page 173, as follows: The court asked this question:

“The next thing I want to know, then, is assuming that they have the normal amount,” that is an individual with a normal sperm count, “what, if you know, would be the effect [552] on them as to an increased stimulation?” That is by the administration of testosterone, and the answer was this:

“It would do two things. First, it would destroy the seminiferous tubules of the testes and, 2, it would aggravate the growth and dissemination of prostatic cancer.”

Do you agree with that statement or do you disagree with it, at least as to the destruction of the seminiferous tubules? You have testified as to the other.

(Testimony of George E. Fakehany, M.D.)

A. It very rarely has been mentioned to do that; and frankly, I don't know whether or not it does. I don't think anyone knows whether it destroys the seminiferous tubules. I don't know how they could prove it.

Q. Why do you say that?

A. I don't know how in the world the individual could prove it, particularly when you are dealing with human beings.

Q. Now, then, on page 176, this doctor also was asked, "How is male hormone deficiency in any person determined?" And he answered this: "Determined by, first, a careful history, No. 2, careful physical examination and No. 3, there are some laboratory tests that will aid in diagnosis, such as the estimation of 17 ketosteroids in the urine."

Is it your practice when a person complains of the symptoms such as we have described, for you to submit the person to such test, to determine whether he has a hormone deficiency, before prescribing testosterone? [553]

A. I submit them to no tests.

Q. Did you ever hear of an instance of any doctor in this locality who does submit them to such tests as that?

A. Well, there are very few that do, if any. None that I know of.

Q. Now, then, Dr. Heckel stated, page 182, in speaking of prostatic cancer, "In the majority of men, the diagnosis in the majority of instances is by rectal examination.

(Testimony of George E. Fakehany, M.D.)

“Q. Can it be detected in early stages?

“A. Yes. But, in early stages, early prostatic cancer, it may be necessary to supplement the rectal examination with a biopsy.”

Mr. Danielson: Excuse me. What page is that?

Mr. Elson: 182. Q. (Continuing): Now, in your practice, in determining whether a man has a male hormone deficiency, to enable you to decide whether to prescribe testosterone, have you ever performed a biopsy on his testicles?

A. I never have.

Q. Have you ever heard of any doctor, in everyday practice, who has done such a thing?

A. I have not.

Mr. Danielson: Just a moment. I believe that is an error, on page 182. It is not a biopsy on the testicles. It is a biopsy on the prostate, rather than on the testicles.

Mr. Elson: Well, all right. [554]

Q. Biopsy on the prostate, have you?

A. I have never done one.

Q. Have you ever heard of other practitioners at least in this locality performing such an operation for the purpose of determining whether there was a prostatic cancer?

A. Yes, biopsy of the prostate gland. If a doctor suspects that a patient has or might have a prostatic cancer, carcinoma of the prostate gland, he may do a biopsy.

Q. But, is it common practice to do a biopsy

(Testimony of George E. Fakehany, M.D.)

when one has not been able to find it by a rectal examination? A. No, certainly not.

Q. How would you go about, then, to perform a biopsy of the prostate?

A. Well, biopsy on the prostate gland is commonly done by inserting an instrument through the penis and cutting a piece of the prostate gland.

Q. And then subjected to test?

A. It is a laboratory test, by a pathologist.

Q. In medical practice, as you have found it, are you able to say whether a large percentage of medical work is specific for certain conditions, or whether it is based on hypothesis, conjecture and hopes?

A. Well, some of our work is specific and exacting, but a large part of it is based on trial and error.

Q. Would you be able to form an estimate as to approximately [555] what percentage would be based on trial and error?

A. Well, I would say half of it.

Q. Now, then, another witness, Dr. Glass, stated here that in his opinion——

Mr. Danielson: What page?

Mr. Elson: Well, I don't know. I haven't any recollection as to any particular page, but he stated that in substance, that estrogen was an absolute prerequisite to the growth of a breast cancer. Do you agree with that opinion? A. I do not.

* * *

Q. (By Mr. Elson): Why don't you agree with that opinion?

(Testimony of George E. Fakehany, M.D.)

A. Well, the reason I don't agree with him is that he has never been able to prove it, nor has any doctor been able to prove it. I would like to see it, if they can prove it, but it is merely a hypothesis so far as I am concerned, it is merely his opinion.

Q. In your opinion, would a dosage of 5 milligrams a day of alpha estradiol be dangerous in accelerating the growth of a breast cancer, cervix or uterus? [556]

A. No. Frankly, not my opinion, but I know that some doctors think that it might.

Q. Have you ever administered alpha estradiol or estrogen? A. I have.

Q. Have you ever encountered any adverse results from the administration of them?

A. I have never.

Q. Have you ever administered dosages of that size or larger?

A. That size and larger.

Q. What is your common practice as to dosages larger or of that size?

A. Well, that is an accepted dosage.

Q. In cases with .1 milligram of alpha estradiol to be taken three per day, for 10 days and thereafter one per day, in your opinion, would that dosage be dangerous in accelerating the growth of a breast cancer, cervix or uterus, that is .1 milligram?

A. .1?

Mr. Danielson: Will you repeat the dosage again, Mr. Elson?

Q. (By Mr. Elson): Three, which would be 3 tenths per day.

(Testimony of George E. Fakehany, M.D.)

The Witness: 3 tenths?

Q. (By Mr. Elson, Continuing): For a period of 10 days [557] and thereafter 1 tenth per day.

A. Well, frankly I would use it, regardless. I know this, that the literature warns that it might do those things, but inasmuch as they have never been able to show anything concrete in this respect, I continue to use it until they can prove that it does or until my experience shows me that it does.

Q. 1 tenth of a milligram is very small, is it not?

A. You mean 1 tenth of a milligram of alpha estradiol?

Q. Yes. A. It is.

Q. Do you have any opinion as to whether or not 1 tenth of a milligram taken three times a day, as I have just mentioned, and then one per day after 10 days, is enough to be effective or ineffective?

A. Well, I think that should help a patient.

Q. Well, in regard to these dosules that are used for breast development, I show you here Government's Exhibit 3 which pertains to Count 3 and it is a photostatic copy of the label on the dosules that are involved here. I wonder if you would read that?

Mr. Sturzenacker: Here is the original. He can read it a little better.

The Witness: This is the original.

Mr. Neukom: What exhibit? [558]

Mr. Struzenacker: No. 3.

Q. (By Mr. Elson): Have you ever used such a product? A. I have.

(Testimony of George E. Fakehany, M.D.)

Q. With what result?

A. Well, frankly, ambiguous results.

Q. You mean it works in some cases and doesn't in others?

A. Well, I would say that an occasional patient thought that they experienced a response from it, but I have had many unsatisfactory results from it.

Q. What do you mean, unsatisfactory?

A. Well, it just didn't seem to do anything.

Q. Is that unusual with almost anything?

A. Well, naturally, a lot of drugs will produce some favorable results—or no results, I will put it that way.

Q. And the same would be true with testosterone if a person was not suffering from a hormone deficiency?

A. That is correct.

Q. By the way, have you ever taken any testosterone yourself?

A. I have.

Q. For how long, or when do you take it, put it that way?

A. Well, practically whenever—once in a while the drug houses send us what we call their physicians' samples, [559] to try ourselves, you know, and I usually consume those myself and on occasions I give them to patients.

Q. Did you take them for any particular purpose?

A. Well, we take them naturally because we think that they will stimulate us and make us feel better, possibly stimulate your libido.

(Testimony of George E. Fakehany, M.D.)

Q. Have you noticed that they had any such effect? A. Well, I thought they did.

Q. Now, then, Doctor, in connection with this .1 of a milligram of alpha estradiol, the complaint alleges that it may cause uterine bleeding and, by the way, did you ever encounter any adverse results from taking testosterone? A. I never did.

Q. (By Mr. Elson): Now, Dr. MacDonald testified, at page 129, around in there, and the substance of his testimony was this, that the taking of that quantity of alpha estradiol might cause bleeding, uterine bleeding, and that the danger of it would be that he would be unable to know whether the bleeding was as a result of a malignancy or something else. Now, would you consider that if a woman took alpha estradiol and encountered uterine bleeding, that that would be a dangerous thing to her? A. It is a warning sign.

Q. Yes, but let me put it this way: Is it unusual for a woman who is suffering from a malignancy to bleed? [560] A. It is quite usual.

Q. That is, as a matter of fact, one of the things that you look for, isn't it? A. That is correct.

Q. Would it be fair to say, then, Doctor, if a woman bled and came to you, regardless of the cause of her bleeding, that she had been endangered or helped in the sense of enabling the doctor to discover some malignancy or something wrong with her?

A. I don't understand your question.

(Testimony of George E. Fakehany, M.D.)

Q. Here is a woman who has taken alpha estradiol. She commences to bleed.

A. How old is the patient? Is she past the menopause?

Mr. Elson: No. Any patient. She comes to the doctor and complains, says that she is bleeding, the doctor asks her what she has been taking and she says alpha estradiol, .1 of a milligram. Do you think that the mere fact that that estradiol might have caused uterine bleeding was dangerous to that woman's health? A. No, I do not.

Q. Why?

A. Well, naturally, if a woman is bleeding, you are going to stop the use of the drug, but we know this, that many times, when you do start the use of estrogen on patients, they will bleed, and we always discontinue the use of it in [561] those particular cases, because this bleeding very often signifies that they already have a carcinoma of the uterus. Many times they will bleed and they do not have a carcinoma of the uterus, but, due to the fact that sometimes they do bleed when you use the female hormones, you always discontinue the use of it.

Q. But the fact that they do bleed, in your opinion, is not a dangerous thing to their health?

A. No. Certainly not. If they do bleed, we usually do a curettement to determine if there is a cancer there.

Q. Doctor, you mentioned in the early part of

(Testimony of George E. Fakehany, M.D.)

your testimony, I think, about the male going through change of life.

A. That is correct.

Q. Is that more ordinarily known as the male climacteric?

A. Well, that is a question of much discussion in literature. The female we definitely know has a menopause. They definitely go through a change of life and the symptoms there are very pronounced in most cases, and they occur at a certain age, and the symptoms are more or less uniform. However, in the male, no such condition exists. It doesn't come at a certain age. The symptoms might vary, and for this reason, some of the literature suggests that the male does not have a climacteric; others suggest that they do have and it is between [562] the ages of 50 and 60 and the symptoms are so and so, and such and such. But, for the most part, the literature suggests that the male does go through a change of life.

Q. And have you found that men in those decades such as you mention, who complained of these symptoms, were benefited by the administration of testosterone?

A. Not all of them. Many of them were.

Q. But many of them were and some of them weren't? A. That is true.

Q. But would you conclude from those that were not, that they were not suffering from a hormone deficiency? A. That is correct.

(Testimony of George E. Fakehany, M.D.)

Q. In other words, they were not going through change of life or a climacteric?

A. At least their symptoms were not from that.

Mr. Elson: Cross-examine.

Cross-Examination

By Mr. Danielson:

Q. Doctor, let us assume from the beginning that in the treatment of your patients, you do try to benefit them. A. I certainly do.

Mr. Danielson: So we can dispose of that point right now.

Mr. Elson: I did not get your question.

Mr. Danielson: That I will say that the doctor does try [563] to benefit his patients in treating them; there is no other motive.

Q. Doctor, you studied at Chicago, I believe, is that correct? A. I did.

Q. I gather that you are possibly acquainted with Dr. Charles Huggins, at least by reputation.

A. Yes, sir.

Q. Do you consider him to be an authority in his field?

A. Yes, he has done a lot of work. I don't agree with everything he has done, but he has done some good work.

Q. You consider him, however, to be an eminent authority in his field, do you not?

A. Yes, he is considered to be an eminent authority.

(Testimony of George E. Fakehany, M.D.)

Q. Are you acquainted, either personally or by reputation, with Dr. Elmer Belt of Los Angeles?

A. Yes, I know Dr. Belt.

Q. Do you know him personally?

A. Well, yes, not too personally. He is an acquaintance.

Q. Do you consider Dr. Belt to be an authority in the field of neurology?

A. He is considered a good, competent urologist.

Q. And you likewise consider him that, I presume? [564]

A. I do.

Q. Now, in Chicago do you know, by any chance, Dr. Norris J. Heckel of the University of Illinois?

A. No, I don't know him.

Q. You do not know him? A. No, sir.

Q. Are you familiar with his writings?

A. I have seen many of his writings.

Q. He is likewise considered to be an authority in this particular field, is he not?

A. I think he is.

Q. And lastly, are you acquainted or do you know Dr. Ian Macdonald, a local doctor?

A. Yes, I know Dr. Macdonald.

Q. He is likewise considered to be an authority in his particular field?

A. He is a urologist. I think he specializes in cancer, doesn't he?

Q. That is correct, female, I think.

A. Yes.

Q. He is a member of the Therapeutics Trials Committee, is he not?

A. I believe he is, yes.

(Testimony of George E. Fakehany, M.D.)

Q. Now, Doctor, you mentioned that you do not conduct any experiments with your patients. May I ask you this: Do [565] you personally do any clinical research work?

A. Well, I think every doctor considers his own practice more or less research.

Q. That is in his field?

A. Individual research, that is correct.

Q. In either the field of the prostate or the testes or in the female genitalia or in endocrinology, is that not correct?

A. That is correct.

Q. Doctor, are you a urologist by specialty?

A. I am not.

Q. Are you an endocrinologist?

A. I am not.

Q. Or a gynecologist?

A. No, but I practice all three.

Q. As a general practitioner?

A. As a general practitioner.

Q. You are a general practitioner. Now, Doctor, you have testified that you are a medical examiner, either are or were, or you have been, I do not recall, either or both?

A. I am.

Q. You are a medical examiner for Technicolor, Goldwyn, RCA, I believe at least during the war you mentioned Hughes Aircraft?

A. Yes, Hughes Aircraft. [566]

Q. What were your general duties as such?

A. Well, we do pre-employment physical examinations on people seeking employment.

(Testimony of George E. Fakehany, M.D.)

Q. Is this a general physical examination?

A. General physical examination, that is correct, and——

Q. And is that your——

* * *

The Witness: And actually we take care of all their industrial accidents, in other words, if anyone is injured at the plant or sick at work, we take care of them.

Q. (By Mr. Danielson): That is, people who also complain or become ill while at work?

A. While at work, that is correct. We do 100 per cent of that now, and we do a large portion of their private practice. Of course, many of them have their own doctors. Some of them haven't. Usually those that haven't will go to the company doctor.

Q. You have your own offices, do you, and these various concerns refer their personnel to you?

A. Yes. They send their work to me, because it would be impossible to be at all of them at the same time.

Q. Yes. I gather that would be correct. [567]

In this connection, do you call that industrial medicine?

A. Well, industrial medicine just refers to the industrial accidents, but it is actually private medicine, private practice.

Q. Well, in connection with these referrals by these three or four or more companies for whom

(Testimony of George E. Fakehany, M.D.)

you work, you do not in that particular practice handle any chronic cases, is that not correct?

A. Yes, we do have a few chronic cases. Of course, for the most part, employees are younger people.

Q. They are on the job? A. That is right.

The Witness: I was going to say, for the most part, people that are working are younger people and healthy people.

Q. (By Mr. Danielson): I thank you for bringing that up, as that takes me right to my next point. I was going to ask you, what is the average age of these persons whom you examine physically?

A. That varies, too. Now, of course the average age is younger than it was during the war. During the war it was anywhere from 17 or 18 to 80 or 85.

Q. But, under the present circumstances?

A. Under the present circumstances, I would say that the average is from 18 to I would say 50, maybe an occasional [568] in the 60s.

Q. The bulk of them are in the younger age groups?

A. In the younger age groups, that is correct.

Q. Let us say the upper 'teens or in the 20s or 30s? A. For the most part, yes.

Q. Thank you. Now, Doctor, how big is a prostate, a normal prostate?

A. Let's see, I will try to compare it. I would say the normal prostate gland is the size of a normal plum.

(Testimony of George E. Fakehany, M.D.)

Q. The testimony has been here, I think you may agree with this, by Dr. Belt, that the normal prostate is about the size of a chestnut. Would that be approximately correct?

A. A chestnut, well, I am not too familiar with chestnuts.

Q. Well, I will go along with you on the plum.

A. Okay.

Q. I am not too familiar with the chestnuts myself.

A. All right.

Q. There are lots of plums, of course. About how big?

A. I would say about this round (indicating).

Q. That is the equal of about how round?

A. In diameter, the size of a silver dollar.

Q. A silver dollar, you would say?

A. That is correct.

Q. Well, then, before you can detect a carcinoma by [569] palpation, it would have to be the size of a grape or acorn. That would be getting up to about a third or fourth of the size of the prostate.

A. No.

Q. Maybe almost half the size of the prostate?

A. Well, I would say it would have to be, well, about a quarter of the size of the gland, before you could feel it. I wouldn't say that I could feel one any smaller than that. Maybe there are those that can, but I certainly would not be sure of anything that I felt any smaller than that.

Q. What is the purpose of this palpation examination?

(Testimony of George E. Fakehany, M.D.)

A. The purpose of the palpation is to determine the size and configuration of the prostate gland, and to see if there are any stony, hard substances that are in it. The palpation is usually done with right or left index finger.

Q. It is by touch, the sense of feeling?

A. That is right, the sense of feeling. It is like feeling a sack and trying to feel what is in it. That is exactly what you are doing.

Q. You take into your consideration size, also, do you not?

A. Size, that is correct.

Q. If the size of the prostate is larger than usual, does that or does that not cause you to be suspicious of it?

A. If the prostate is larger than usual, we think of [570] something else, such as hyperthesis of the prostate gland.

Q. (By Mr. Danielson): The prostate gland is usually susceptible to carcinoma?

A. Yes, there is quite a lot of carcinoma of the prostate gland.

Q. Are you familiar with the normal incidence of carcinoma of the prostate?

A. Well, the figures vary on that. I am not sure of the figures.

Q. You have not conducted any clinical research into that?

A. No, sir, I haven't.

Q. As to this blood test which was mentioned for carcinoma of the prostate, I believe that is also known as the acid phosphatase test or the acid alkaline phosphatase test?

A. That is correct.

(Testimony of George E. Fakehany, M.D.)

Q. You have mentioned that you have never performed it yourself. A. I never have.

Q. And you are not personally aware of any doctors here who have performed it?

A. I am not sure, but I think Dr. Belt and possibly a couple of other leading urologists use that test.

Q. If Dr. Belt says he does use it——

A. I wouldn't frown on it. [571]

Q. You would not think it would be improbable, would you?

A. I wouldn't frown on it. That is right.

Q. I say, you would probably admit that that would be true, then? A. That is correct.

* * *

Q. (By Mr. Danielson): Now, Doctor, you have testified that you have no personal opinion as to whether the use of the hormone will accelerate the growth of an early or an incipient carcinoma of the prostate, is that correct?

A. Personally I don't know whether or not it will.

Q. You do not know whether or not it will?

A. That is right.

Q. Well, you are aware of the fact that there is at least a respectable portion of informed medical opinion holding that it will, is that not correct?

A. That is right, and there are quite a few say they don't know, and there are some that say it doesn't.

Q. But you are aware of the fact that there is a respectable portion saying that it will?

(Testimony of George E. Fakehany, M.D.)

A. I certainly am.

Q. Have you yourself done any clinical research or laboratory research into that particular subject? A. No. I have done none.

Q. None. Your opinion, then, would be based entirely on your study, reading and so forth?

A. Exactly.

Q. How many examinations of this type have you given, in your work?

A. Of course that varies. Not so many now.

Q. On an average, what is it, about 25?

A. During the war, it was about 25 a day.

Q. Is this examination a general physical examination, the standards of which are agreed upon by you and the employers, the companies?

A. Yes, it is.

Q. Such an examination would not necessarily include any special examinations, would it? Is it a routine established?

A. Well, that varies again with the organization. Some demand a very demanding examination. Some merely demand [573] an examination for hernia.

Q. But this standard is set up by the company, is that not correct?

A. That is right, they use the so-called general physical examination.

Q. As a matter of fact, if this company required one of these acid phosphatase tests, you would per-

(Testimony of George E. Fakehany, M.D.)

form it? A. I would not recommend it.

Q. If they demanded it, you would perform it?

A. Well, if they demanded it. I doubt if they would.

Q. Well, I am assuming if they demanded it, you would?

A. All right. If they did, I would, then certainly I would.

Q. Doctor, do you perform any surgery on the prostate? A. No, I don't.

Q. You have never removed a prostate, is that right?

A. No. I have assisted. The prostate glands are only removed by urologists.

Q. And you are not a urologist. I believe you testified to that.

A. I am not a urologist. That is correct.

Q. Do you frequently examine diseased prostates, I mean prostates for carcinoma?

A. Not frequently, carinoma of the prostate isn't frequently encountered in the normal private practice. [574]

Q. Then, you have not had a great deal experience with them, then, is that correct?

A. Well, I have had experience in the last 12 or 14 years, but not a great deal, no, I wouldn't say a great deal.

Q. Do you treat cancers of any kind?

A. I do. I treat cancers of any kind, anywhere where I may find them.

Q. Is it or is it not true that if a cancer is de-

(Testimony of George E. Fakehany, M.D.)

tected at an early stage, it is more susceptible to therapy? A. It certainly is.

Q. The smaller they can be found, the better they are? A. That is correct.

Q. Would you consider a cancer to be an early cancer if it is small enough so that it is susceptible to some beneficial therapy? [575]

* * *

The Witness: Yes, but it is a little ambiguous, frankly, because the size of a cancer does not necessarily determine the period of growth. In other words, you are presuming in your question that an early cancer is a small one. That doesn't necessarily follow.

Q. (By Mr. Danielson): No, some early cancers can be fairly large, then, is that correct?

A. That is right, and some late cancers can be small.

Q. In other words, the size of a cancer does not necessarily refer to its age?

A. That is correct.

Q. Although there could be some relation?

A. Generally speaking, there is a general relation, but it doesn't necessarily follow that an early cancer is a small one.

Q. Well, an early cancer could be as large as a grape, then?

A. Well, of course, "early" is a little ambiguous, too.

Q. Just on the basis that you just told us, couldn't an early cancer be as large as a grape?

(Testimony of George E. Fakehany, M.D.)

A. That is correct.

Q. Or even an acorn?

A. That is correct.

Q. Now, as to the subject of sterility, Doctor, you have testified that the use of the hormone, of testosterone, [576] would reduce the sperm count.

A. That is correct.

Q. But that you do not know whether it would cause sterility?

A. That is correct.

Q. Is it not true, Doctor, that sterility or fertility is sort of a matter of relative sperm count?

A. That is correct. That is correct.

Q. If the sperm count is reduced below some figure, I believe it is about 150,000,000—

A. Yes, I think that is it.

Q. Then, you are considered clinically sterile, but above that clinically fertile, is that correct?

A. That is correct.

Q. Do you not believe, Doctor, that it is possible with the prolonged use of testosterone to reduce this sperm count below 150,000,000?

A. Yes, I think that the use of testosterone will reduce the sperm count, but I doubt if it will reduce it sufficiently, enough to produce sterility.

Q. Below 150,000,000?

A. Well, I don't know. It is hard for me to answer that. I have never done a sperm count on these patients.

Q. I see.

A. I am testifying from what I have read in the literature. [577]

(Testimony of George E. Fakehany, M.D.)

Q. You have not conducted any independent research? A. That is correct.

Q. Into the subject of sterility?

A. That is correct.

Q. Or on the subject of the effect of testosterone on fertility or sterility?

A. That is correct. As far as my personal experience is concerned, I have never had any adverse results in that way, I have never seen it make any of my patients sterile.

Q. Now, I want to ask you a question there, Doctor, in considering a patient who, let us say, wants testosterone and you know of no immediate pathological condition which would contra-indicate testosterone, but in view of the indefinite knowledge as to what effect this will have on sterility and yet knowing that it will reduce the sperm count, would you recommend testosterone to a man who wished to procreate, to whom fertility was important?

A. No, I don't believe I would.

Q. Now, you testified that the male sex hormones at least has some value in cases of male hormone deficiency? A. It appears to have.

Q. Do you have any opinion as to whether a lay person can determine whether he has a hormone deficiency?

A. Well, he may have an idea that he has. [578]

Q. But as to whether he can diagnose it?

A. I don't think he could diagnose it.

Q. As a matter of fact, diagnosing of a male sex

(Testimony of George E. Fakehany, M.D.)

hormone deficiency is a rather difficult examination, isn't it?

A. Well——

Q. Have you not testified, Doctor, that under certain symptoms that a person may have different deficiencies and then I believe, to use your words, by the use of trial and error you determine whether or not the hormone is beneficial?

A. That is correct.

Q. And is not the reason for that that the determination of whether or not a person has this deficiency is oftentimes very difficult?

A. I did not understand the last.

Q. To go in the back door on this——

A. All right.

Mr. Danielson: We will agree, I presume, that a castrate has a male hormone deficiency.

The Witness: That is correct.

Q. And likewise, a hypogonad has male hormone deficiency?

A. Correct.

Q. Now, take a person who is apparently normal, who apparently possesses all of his organs, the doctor, to determine whether or not there is such a deficiency, takes what [579] steps, what steps must be taken, how would you determine it with such a person?

A. In a hypogonad?

Q. No. In a person who is apparently normal in his physical makeup.

A. Well, there is actually no way of determining exactly whether or not he has. You must listen to the patient's story and try to evaluate the symptoms that he presents and if his symptoms fall into a cer-

(Testimony of George E. Fakehany, M.D.)

tain category, we merely presume that he has a male hormone deficiency.

Q. And that is when this so-called trial and error procedure comes into play?

A. That is correct.

Q. But prior to that, though, would you not try to determine whether or not a man has a cancer of the prostate?

A. I would not necessarily look for a cancer of the prostate. I would talk to the patient and actually, if he had any symptoms that suggested prior cancer of the prostate, I certainly would investigate.

Q. And how do you determine those symptoms, by the use of what method? That is by rectal examination?

A. Palpation, correct.

Q. And if you found any suggestion of carcinoma of the prostate, would you then recommend testosterone or prescribe it? [580]

A. I don't think I would. I would respect the literature that I read.

Q. Is it correct, Doctor, then, the use of a male hormone or any hormone, for that matter, should be what is known as a replacement therapy?

A. That is correct.

Q. To replace that which Nature no longer provides, at least not in adequate quantities?

A. That is correct. [581]

Q. As to these symptoms that were mentioned by Mr. Elson, the flushes, sweats, nervousness, irritability and nocturia and so forth, isn't it a fact

(Testimony of George E. Fakehany, M.D.)

they are also the results of something besides hormone deficiency?

A. Any one of those symptoms may be present in anyone or may indicate another disorder. However, that confusion is usually seen in the so-called male climacteric.

Q. How about in anxiety states?

A. An anxiety state might present any symptom or combination of symptoms.

* * *

Q. (By Mr. Danielson): Are not those symptoms of exophthalmic goiter?

A. Some of them are.

Q. How about fatigue states? [582]

A. A fatigue state is one.

Q. And fatigue is rather common in the present day and age, isn't it? A. Yes.

Q. How about tuberculosis?

A. That is a common symptom of tuberculosis.

* * *

Q. In your testimony as to your examination of your patients, Doctor, you mentioned that you talked to them a few minutes. I gathered that you meant by that that you were taking their history? [583] A. Yes, sir; that is correct.

Q. And your purpose is to benefit your patients, when you speak of trial and error. You do not by that mean that you do not attempt to make an accurate diagnosis? A. Certainly not.

Q. I just wanted to make that clear. Your atten-

(Testimony of George E. Fakehany, M.D.)

tion was directed on direct examination to the testimony of Dr. Huggins to the effect that certain experiments were conducted in some cases in hospitals in which he was employed.

A. Yes; I heard that.

Q. That is a usual procedure, is it not, insofar as you know?

A. Do you mean to conduct these experiments?

Q. To talk about their history is not the sort of thing you were referring to by trial and error, is it?

A. That is correct; it is not.

Q. There are, obviously, fields in medical science which are not yet known?

A. That is true, and certain medicines are prescribed in order to try to obtain the best results.

Q. And that is for the purpose of determining what is the therapeutic effect of those medicines?

A. That is correct. That is common.

Q. In regard to estrogens, the female sex hormones, have you ever conducted any clinical or laboratory research into [584] that field? A. No.

Q. Your statements and opinions, then, are based on your reading, study and possibly discussions with other doctors? A. Correct.

Q. And that would include, then, your lack of clinical experiment and would include or would, likewise, apply to any experiments in connection with the female genitalia or the male genitalia?

A. Yes; that is correct.

Q. As to impotence, I believe you stated that impotence is frequently of psychogenic origin?

(Testimony of George E. Fakehany, M.D.)

A. I did.

Q. And, likewise, you felt that, when you gave the male hormone, you sometimes had some alleviation of the impotence?

A. At least, the patients have had it.

Q. You say the patients have told you they did have a benefit?

A. That is correct.

Q. Is it not true, Doctor, that in cases of psychogenic origin, any type of treatment in which the patient has faith will sometimes produce a beneficial result?

A. That is true of any disorder.

Q. Isn't that true of the old-fashioned sugar pill that [585] was given years ago?

A. It is true that the sugar pill will benefit patients.

Q. Are you not aware of the fact that among lay people at least there is some belief that oysters as such have a beneficial effect on people?

A. Yes; you will hear that.

Q. And such effects are not directly traceable to testosterone?

A. We try to differentiate. We try to determine whether or not the results are actual results or whether they are those of a psychogenic patient merely stating he got results. I think every doctor tries to determine those.

Q. As to the testimony relative to the destruction of the semeniferous tubules, do I understand that you do not know how such would be determined?

A. That is correct, in man.

(Testimony of George E. Fakehany, M.D.)

Q. How about a biopsy? Would that not determine it?

A. Well, you would have to take a biopsy before and one after.

Q. If there were a pre-treatment biopsy and a post-treatment biopsy, that could be determined?

A. I would say it could.

Q. Are you familiar at all with the work of Dr. Warren O. Nelson, of the University of Iowa, clinically?

A. No; I am not. [586]

Q. However, if you were to hear him testify that he has performed such experiments, you would not doubt them for that reason alone?

A. No; I certainly would listen to them eagerly.

Q. As to determining whether there is such a thing as a male sex hormone deficiency, your attention was directed to the testimony of Dr. Heckel, who said, on page 176, "Q. Now, Doctor, how is male hormone deficiency in any person determined?"

"A. Determined by, first, a careful history——"

You have no disagreement with that, have you?

A. No.

Q. "No. 2, a careful physical examination——"

Q. You do not disagree with that, do you?

A. No.

Q. "And No. 3, there are some laboratory tests that will aid in diagnosis, such as the estimation of 17 ketosteroids in the urine."

You have no disagreement with that, Doctor, have you?

A. No; I haven't.

Q. You are familiar, I am confident, with the physiology of the testes?

A. Yes, sir; I am.

(Testimony of George E. Fakehany, M.D.)

Q. And that the sperm are produced in a different part of the organ than the testosterone is produced? [587]

A. That is right.

Q. Would it not be possible by a biopsy examination to determine whether the testes are still able to produce testosterone?

A. Under controlled laboratory conditions, they can, with biopsy, determine the sperm count and the shape and configuration of the sperm, but I don't think they can isolate the testosterone.

Q. No, I say by a biopsy of the testicle to determine whether the interstitial cells are still in a normal state.

A. I think they can determine quite a bit.

Q. If you heard testimony of a doctor who said he had devoted about 10 to 15 years to such research and was able to determine that, would you have any reason to doubt it?

A. I wouldn't doubt him but I wouldn't necessarily accept him, either.

Q. You have never performed any such research yourself?

A. I have not.

Q. Is it not true, Doctor, that there is no necessary connection between impotence on the one hand and sterility on the other?

A. That is right.

Q. The fact that a man is impotent doesn't necessarily mean that he is sterile? [588]

A. That is correct.

Q. And vice versa?

A. That is correct.

Q. You gave an opinion, Doctor, as to whether 5 milligrams per day of alpha estradiol would have any effect—

(Testimony of George E. Fakehany, M.D.)

Q. (By Mr. Danielson): Excuse me; as to whether 5/10 of a milligram per day of alpha estradiol would have any effect upon a female. Have you conducted any experiments to determine that point?

A. I haven't conducted any experiments.

Q. You have administered different dosages of the female hormones? A. I have.

Q. Is it not true that you found that the therapeutic effect of the hormone varies in different people? A. It does.

Q. That is, some people seem to respond more quickly or easily than others? A. Correct.

Q. A small amount has as much effect on one person as a large amount may have on another person? A. Correct.

Q. As to the kind of hormone dosules which I believe [589] you said you have used, I believe you stated that your results have been ambiguous but that some of the patients said they thought they noticed some beneficial results? A. Yes, sir.

Q. Was that for cosmetic purposes, to develop the bust?

A. Yes; that is what it is commonly used for.

Q. You mentioned that some of your patients stated that, in their opinion, there was some benefit. Did you ever see any benefit, in your own opinion, from the use of this Menformon Dosule?

A. The patients don't usually continue it long enough for a doctor to actually take a look at a woman's bust and determine whether it has been

(Testimony of George E. Fakehany, M.D.)

enlarged or not. In other words, if there was an enlargement—after all, we don't measure a woman's bust when she comes into the office. We must take her word for that sort of thing, the size of it.

Q. In the cases you have cited, have you ever seen this cosmetic effect?

A. No; I can't say I have.

Q. As to the use of hormone by yourself, may I ask you how long a therapy you have taken over one period of time?

A. Oh, I have taken them two or three weeks at a time.

Q. Would that be a tablet per day?

A. About two tablets per day.

Q. Doctor, if you had any suspicion at all that you had [590] an early or incipient carcinoma of the prostate, would you have done that, this is, taken that treatment?

A. I doubt if I would because the mere fact that someone else suggests it might have some bad effect or do some injury would be enough for me not to try it.

Q. Would you consider that good professional practice at least?

A. I would say so.

Q. As to the use of alpha estradiol in females in which there is uterine bleeding, isn't that bleeding at least one symptom of a cancer of the genitalia?

A. It is.

Q. And, under those circumstances, you would immediately stop the use of that drug, would you not?

A. I would.

(Testimony of George E. Fakehany, M.D.)

Q. As to the male climacteric—you stated that in the female there are definite findings in case of the climacteric? A. Correct.

Q. That would be a cessation of ovulation, for one thing?

A. That wouldn't be a finding clinically speaking. Clinically speaking, it is a cessation or stop of the menses.

Q. Something happens to the ovary at that time, doesn't it? [591]

A. Yes; they shrink up.

Q. And they cease producing hormones, do they not? A. That is right.

Q. Now in comparable cases in men, if there were a male climacteric, what would be the finding or phenomena in the male?

A. We presume that the testes would shrink up.

Q. And would no longer produce sperm?

A. No longer produce testosterone.

Q. How about the sperm?

A. The sperm count is diminished.

Q. In the female the ovary would no longer produce its eggs? A. No, sir.

Q. As a matter of fact, you have conducted sperm counts at least in college? A. Oh, yes.

Q. Is it not true that in men of advanced years there is frequently a substantial sperm count?

A. Yes; there might be.

Q. Have you ever conducted any such tests?

A. Well, frankly, I don't recall conducting them

(Testimony of George E. Fakehany, M.D.)
in any elderly gentlemen but I know for a fact that some of them do have a good sperm count.

Q. You have never made any study of that particular [592] subject? A. No; I haven't.

Mr. Danielson: No further questions.

Mr. Elson: I just have one or two questions.

Redirect Examination

By Mr. Elson:

Q. Mr. Danielson asked you if fatigue and so on wasn't usually associated with a certain type of goiter and tuberculosis.

Mr. Danielson: That is a misinterpretation. I will straighten it out, if you wish. At that point I was referring to the symptoms which have been frequently mentioned and are contained——

Mr. Elson: Yes, nervousness and so on. I think you stated that they were associated with a certain type of goiter and with tuberculosis.

Mr. Danielson: That is correct, those same symptoms.

Is that not correct, Doctor?

The Witness: No. You were referring to the symptom of fatigue.

Mr. Danielson: Then, I wish to correct it for that wasn't my intention. I referred to nervousness and irritability.

The Witness: No; not all of them would be symptoms of those diseases. I told you some of them might be and you asked me about fatigue and

(Testimony of George E. Fakehany, M.D.)

I told you fatigue would be a [593] symptom, too, of tuberculosis and exophthalmic goiter.

Mr. Danielson: I am interested in the symptoms which are reflected in Government's Exhibit 1, flushes, sweats, chills, lack of sexual power, impaired memory, inability to concentrate on activities or tendency to evade them, nervousness, depression, general weakness and poor physical strength. Are not those symptoms likewise the symptoms of a state of fatigue?

The Witness: I would say that some of them were but not all of them.

Mr. Danielson: Some of them are?

The Witness: That is correct.

Mr. Danielson: And, likewise, some of them are of tuberculosis?

The Witness: Correct.

Mr. Danielson: And some of them are of this goiter I referred to?

The Witness: That is right.

Mr. Danielson: That is all.

Q. (By Mr. Elson): How many men in your practice that have come to you complaining of these symptoms, for whom you prescribed testosterone, had goiter or tuberculosis?

A. Frankly, I can't recall any that did have.

Q. As a matter of fact, if they did, you would have adopted a different mode of treatment, wouldn't you? [594]

A. They are quite easily detected.

Mr. Elson: That is all.

(Testimony of George E. Fakehany, M.D.)

Recross-Examination

By Mr. Danielson:

Q. About how many of them had fatigue, Doctor? A. Quite a few of them.

Mr. Danielson: Thank you. That is all.

The Court: Do you prescribe the drug testosterone for loss of memory or failure of memory?

The Witness: In a man past 55, I would say yes. With no other obvious cause for that symptom, I would.

The Court: I have no other questions.

Mr. Elson: I have no further questions. [595]

* * *

Mr. Elson: Your Honor, the clerk tells me that the record does not show Defendants' Exhibit B for identification to be in evidence. That is a report of the State Board of Pharmacy we discussed this morning. So that now I offer Defendants' Exhibit B for identification into evidence.

The Court: It is in evidence.

The Clerk: Defendants' B in evidence.

(The document referred to was marked Defendants' Exhibit B and received in evidence.)

Mr. Elson: Dr. Paul Travis.

DR. PAUL EDWARD TRAVIS, M.D.
called as a witness by and on behalf of the defendants, having been first duly sworn, was examined and testified as follows:

The Clerk: Your full name?

A. Paul Edward Travis.

Direct Examination

By Mr. Elson:

Q. Doctor, are you a medical doctor?

A. Yes, sir.

Q. And you have an M.D. degree?

A. That is right.

Q. Will you please state the schools that you went to? [596]

A. Undergraduate, University of Southern California, A.B. degree in 1941, University of Iowa——

Q. Just a minute. In connection with your A.B. degree, was there any particular honor conferred upon you?

A. I was a member of Phi Beta Kappa, University of Iowa, 1942, Master's degree in physiology, and then back to the University of Southern California for a medical degree in 1946, interned at the Santa Fe Hospital for 12 months and then at the request of the government, spent two years in the service, stationed at the Veterans' Hospital in Phoenix, Arizona, and returned to private practice in 1948.

Q. All right. Now, have you ever used a product known as testosterone, in your practice?

(Testimony of Dr. Paul Edward Travis, M.D.)

A. Yes, sir, I have.

Q. In your private practice? A. Yes.

Q. Did you use it while you were at the Veterans' Hospital?

A. Yes. We used it there, also.

Q. Now, are you familiar with the term known as the male climacteric? A. Yes.

Q. What do you associate with that term in connection with the symptoms of a male?

A. Well, it is the change of life in a man, and—— [597]

Q. And what usually from your experience have you found to be the symptoms that are associated with it?

A. About the same as with the female.

Q. And what would those be?

A. And that is a loss of libido.

Q. Libido, for the record, is what?

A. Well, libido is sexual drive; loss of libido, a feeling of a sense of not well being, the patient doesn't feel well, usually they are nervous, irritable, they have insomnia, they are not able to sleep well at night. They just come in and say, "Doc, I don't feel well."

Q. Now, then, have you had patients of middle life, male patients of middle life, come in to you and complain of some of those symptoms?

A. Oh, yes.

Q. And have you on such occasions, not on all but on some of those occasions, prescribed testosterone to them? A. Yes.

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. And did you afterwards see those patients, some of them? A. They came in, yes.

Q. And with some of those patients did you find that the symptoms appeared to be relieved?

A. Very definitely.

Q. Now, you know what I mean when I speak of hypogonadism? [598] A. Yes.

Q. A person who is a hypogonad, who is suffering from a male hormone deficiency?

A. Not necessarily. There are several hormones tied up in hypogonadism.

Q. Well, we will say that if a person's scrotum was not the normal size of a person of his age, his penis was not of the normal size of a person of his age, he did not have the distribution of body hair that would be associated with the normal individual of his age, his muscular development was not that of a person of his age and his voice was a high-pitched voice, in your opinion, would the male sex hormone testosterone be of any aid to that person?

A. Oh, yes, along with other products.

Q. Now, assuming that a person is lacking in male hormone deficiency, he has a male hormone deficiency and complains of a lack of sexual power and impotence, in your opinion would testosterone be of assistance to that individual in overcoming it?

A. Definitely.

Q. People suffering from male hormone deficiency, has it been your experience that testosterone improves their physical and mental work?

(Testimony of Dr. Paul Edward Travis, M.D.)

A. Oh, very definitely, yes. [599]

Q. Does it appear to impart a renewed vigor to the individual? A. Yes.

Mr. Danielson: Your Honor, I object to this. I suggest that counsel ask the witness what the drug does rather than tell the witness what the drug will do. It is a little bit too leading, I believe, your Honor.

Mr. Elson: All right.

Q. You have mentioned some of the symptoms that are associated with this deficiency other than those that you have testified to. Can you at the moment think of any others?

A. Well, it definitely gives them a better night's rest, many of them gain weight on testosterone, males who have been losing weight, and it seems to increase their appetite and impart a general sense of well-being and they are a little bit better able to concentrate, and such things like that.

Q. Now, when a person comes to you and complains of symptoms such as we have mentioned, what do you ordinarily do, what would you do with such an individual, starting at the commencement?

A. Try him out on the drug and if it helped him, that certainly would be the answer.

Q. And what would be the length of time that you would expect the man to have some relief, if he was suffering from such a deficiency? [600]

A. You mean the length of time that it would take to obtain relief?

Q. Yes.

(Testimony of Dr. Paul Edward Travis, M.D.)

A. We usually see relief in two to three weeks, upon the usual dosage.

Q. Now, page 39.

The Court: What are your usual doses?

The Witness: I beg your pardon, sir?

The Court: What are your usual doses?

A. We give them, according to the weight of the patient, 25 to 50 milligrams of testosterone a day.

Q. (By Mr. Elson): That would be in tablet form? A. Yes, the methyl testosterone.

Q. Now, the other day, a Dr. Thienes testified for the prosecution as to what in his opinion the general practitioner would do with a man in middle life who complained of some of these symptoms, prior to prescribing testosterone, and I am going to call your attention to pages 39 to 41. This is not verbatim from the transcript, but it is a digest of it. I think you will find it correct.

Assuming a man to be 50 years of age who complains of flushes, sweats, extreme nervousness, inability to concentrate, nocturia, and he goes to his doctor who is an average general practitioner, and no evidence of cancer of the prostate has been diagnosed, Dr. Thienes says that he does not [601] believe that the doctor would prescribe testosterone for a period of time and wait to see whether the symptoms were relieved. Before he would answer that the general practitioner would prescribe it, he would have to know more about what his general examination consisted of, what the urologist had done by way of examination, if the urologist's re-

(Testimony of Dr. Paul Edward Travis, M.D.)

port was that he had palpated the prostate and performed a biopsy and found no evidence of cancer of the prostate and no enlargement of the prostate, and laboratory tests showed that there was a decrease in the secretion of testosterone, even then in his opinion testosterone would not be prescribed by the man's doctor unless there was further evidence of the male climacteric.

Now, is it your practice to follow the route that was testified to by Dr. Thienes before prescribing it under those conditions?

A. No. A general practitioner doesn't have the time nor does his patient usually have the funds to undergo such an expensive laboratory determination, and I never do it.

Q. Do you know of any other practitioners that follow such a routine?

A. Not if they are a busy practitioner.

Q. In the practice of medicine, is it common or uncommon for you, when a person comes in and complains of certain things, to diagnose it to the best of your ability and arrive [602] at what you think will relieve him and then, if that does not work, try something else?

A. Yes, that is the practice of medicine.

Q. And in the practice of medicine, isn't it largely a matter of trial and error?

A. That is all you have got to go by in most instances.

Q. Now, when you were with the Veterans' Ad-

(Testimony of Dr. Paul Edward Travis, M.D.)
ministration Hospital, I think you stated that you gave testosterone? A. Yes.

Q. Will you state the circumstances under which you gave it and how it was given?

A. Well, usually the patients were hospitalized and most of our veterans that were given testosterone were past middle age, with a concomitant physical ailment such as asthma, or bronchiectasis, or a heart condition, whom we felt would give them the added energy perhaps to make ambulatory roll call each morning, because most of them just like to lie around in bed, and by giving them testosterone, it seemed to give them enough energy and a little more libido to be ambulatory so as to go to ambulatory mess, and gave them a sense of well-being and took their minds off their own ailments and made them a little more cheerful.

Q. Did you give any examinations to these patients before giving them this testosterone?

A. We gave just a general physical. [603]

Q. And what does a general physical embrace?

A. Why, eye, ear, nose and throat examination, heart, lungs, abdomen, prostatic examination. That is about all.

Q. By the way, about how long does it take to make a prostatic rectal examination, ordinarily.

A. About 30 seconds.

Q. In your experience have you ever encountered any adverse results from the administration of testosterone? A. No, sir, I haven't.

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. Enlargement of the prostate, as a rule, is that a cancerous condition or something else?

A. As a rule, it is not a cancerous condition.

Q. What is it?

A. Well, doctors like to abbreviate things, they call it prostatic hypertrophy. It is simply a benign enlargement of the prostate. That is the most common cause of the enlargement of the prostate.

Q. The other day, one of the government witnesses, Dr. Heckel (page 173) stated that in his opinion males of middle age do not suffer from a deficiency of the male hormone. Do you agree with that statement?

A. No, I do not.

Q. Have you in your experience found the contrary?

A. Yes. [604]

Q. Now, also Dr. Heckel stated that a male hormone deficiency in any person prior to the prescription of testosterone is determined, 1, by a careful history; 2, by a careful physical examination, and 3, by laboratory tests, such as an estimation of 17 ketosteroids in the urine. Do you follow that examination in determining whether or not a person is suffering from a deficiency prior to the prescription of testosterone?

A. No, because, as I stated before, this has to do with a specialist's laboratory, laboratory tests. I don't do them in my office. I don't have the facilities. I doubt whether the average clinical laboratory in the outlying districts would be capable of doing a 17 ketosteroid.

Q. Is that an established or a rare test?

(Testimony of Dr. Paul Edward Travis, M.D.)

A. It is a rare test.

Q. Do you know of any doctors that run that test prior to prescribing testosterone?

A. Not in my section of town. Perhaps an urologist but not of my knowledge.

Q. This same Doctor Heckel, when asked how cancer of the prostate was diagnosed, answered, at page 182, in substance, as follows, that in the majority of men the diagnosis is by rectal examination, but that in early stages, however, of prostatic cancer it may be necessary to supplement the rectal examination with a biopsy, as there are two other conditions [605] that may simulate an early prostatic cancer; that one is a stone in the prostate and the other is an area of inflammation. In your practice, have you ever performed a biopsy upon a person's prostate to determine whether or not it was cancerous?

A. No; I never have but I have referred patients to an urologist if I suspected he might have cancer of the prostate.

Q. That is after you definitely suspected it on diagnosis that you have made yourself?

A. Yes, sir; that is right.

Q. Is it usual practice, from your experience, for doctors in this locality to perform a biopsy upon a patient's prostate after they have not been able to find it by a rectal examination?

A. I don't think any general practitioner would undertake to do anything like that.

Q. Why?

(Testimony of Dr. Paul Edward Travis, M.D.)

A. For one thing, it requires special instruments, for instance, a cystoscope, and I don't think any general practitioner owns one. Consequently, there are complications from a biopsy which a general practitioner is not prepared to meet. One is bleeding. The prostate is a very vascular organ and after biopsy it is necessary to coagulate the area there in which you take the biopsy. This all, very definitely, is a [606] specialist's technique, and it is a thing I would not be capable of performing myself. I imagine an urologist would be the man to do that, although I don't know whether they do that in their offices or not. It sounds more like a hospital procedure.

Q. From your experience with patients, what do you think a patient's attitude would be towards such a suggestion?

A. He would probably never come back if you suggested it.

Q. In this complaint it is charged that testosterone, 25 milligrams per day or 50 milligrams per day of methyl testosterone, may accelerate the growth of an incipient cancer of the prostate or may cause sterility. From your experience, do you believe it is possible for you to diagnose an incipient cancer of the prostate?

A. I don't know of anyone who can diagnose an incipient cancer.

Q. Will you state why?

A. "Incipient" means at its very beginning or in its early stage, and it is a very difficult thing to

(Testimony of Dr. Paul Edward Travis, M.D.)

contact. Any disease in its incipient form is practically undiagnosable or undetectable.

Q. How large would you think a cancer of the prostate would have to be before you could locate it by palpation? [607]

A. It has to involve one of the lobes before it could be detected. That is about a quarter of the prostate.

Q. Dr. Heckel the other day, starting at page 186, stated, as to a patient coming to a general practitioner, that, in his opinion, the first thing he should do is to make a careful examination of the patient to see if he can find out what is producing the symptoms; that he would make a complete physical examination from head to foot, and, if that produced nothing, he would probably examine the urine to see whether there was any sugar in it, which might give him a clue to diabetes which would produce this sort of symptoms; that, if he assumed there was no sugar, he would then look at the urine to see whether there was albumin in the urine or casts in the urine, which would indicate that the patient, in all probability, would be suffering from Bright's Disease or some kidney disturbance; that then, if nothing turned up, he would take the patient's blood pressure and, if that was normal and his urine negative, he would probably take a blood count to see whether the patient was suffering from anemia or had some blood disturbance; that there might be some indication that the patient had a gastro-intestinal disturbance and an X-ray picture

(Testimony of Dr. Paul Edward Travis, M.D.)

of the stomach or an X-ray picture of the colon should be taken or a basal metabolic test made to discover whether or not he had some disturbance of his thyroid; that such a doctor wouldn't [608] suggest testosterone to the patient to be tried for a period of say four to six weeks and see if those symptoms were relieved, that is, that he might but he shouldn't. In your practice, do you follow the method that has been outlined by Dr. Heckel as a condition precedent to the administration of testosterone?

A. I don't think any general practitioner could afford to go through that rigmarole on any patient before giving such a simple medicine as testosterone.

Q. Do you know of any doctors who do so?

A. No; I don't. A general patient coming in for a little relief of some fatigue, nervousness and so forth, is not prepared to meet a laboratory examination fee of upwards of \$50 for a blood count and so forth. That is shotgun laboratory diagnosis and I don't think any ordinary patient can afford that sort of treatment.

Q. Have you read any of the literature concerning testosterone and its relationship to growth of cancer of the prostate?

A. There are articles pro and con on the subject; yes.

Q. What do you mean by pro and con?

A. Some say that testosterone will accelerate growth of a cancer of the prostate and some say it

(Testimony of Dr. Paul Edward Travis, M.D.)
has no effect and others definitely state it inhibits the growth of cancer of the prostate. [609]

Q. Based on what you have read and from your experience, do you consider testosterone to be dangerous?
A. Absolutely not.

Q. In connection with the subject of sterility, taking the same man, we will say, who comes to you and complains of nervousness, fatigue and so on, as we have discussed, from your experience is the question of sterility or fertility of importance to such a man as compared to being relieved of his symptoms?

A. Certainly not; especially if he is 45 years or over. He has had his family and, if he has not, it is too late anyway.

Q. Is it usual for you to discuss the subject of sterility or fertility with such an individual before prescribing for him?

A. Sometimes, but what they are interested in is their symptoms, not procreation at the age of 45, 50 or 55.

Q. In connection with your practice, you receive considerable literature, do you from the various manufacturers of testosterone, from Ciba, Roche-Organon and Schering?

A. Yes; we get a lot of literature on various drugs daily.

Q. Do you consider that the information contained in that literature is authentic?

A. Absolutely. [610]

Q. It is, so far as you know, the practice of

(Testimony of Dr. Paul Edward Travis, M.D.)

other doctors that you know of to rely upon the literature that is thus furnished to them?

A. As to the general practitioner, that is one of his main sources of current information, the literature from the drug houses.

Q. And that is furnished by what we know as the detail man, is it not?

A. The detail man and then they send it to you through the mail.

Q. We have talked about detail men here. Will you explain to the court what a detail man is?

A. He is a representative from the various drug houses and he calls upon you, the doctor, and brings samples of their various medical products and literature pertaining to those samples, and he tells you how they were developed, what they are used for, their price, and he gives you information regarding the drug. Whether it be new or old or whatever type of drug it is, it is explained to the general practitioner.

Q. On the same subject of sterility, have you in your experience ever found the administration of testosterone to make a man sterile?

A. I don't think I have ever examined for sterility because a man complaining of symptoms referable to the male climacteric has usually passed the age of fertility, and [611] they are not interested in that and never inquire about it. They never come to the doctor and say, "I can't have a child. Why not?" At 45 or 50 they are not interested in that.

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. Do these symptoms you speak of appear to the individual to be really distressing?

A. Absolutely.

Q. Have you examined or read any of the literature on the subject of testosterone and its relation to sterility?

A. Again, that is very controversial——

Mr. Danielson: Just a minute. Will you answer the question directly in this particular case?

The Witness: Yes; I have read it. You get a lot of it.

Q. (By Mr. Elson): Go ahead.

A. But this is controversial.

Q. By that you mean what?

A. Some say it produces sterility. Other doctors claim that it has no effect on fertility, and other doctors even seem to think that it will relieve sterility.

Q. Coming to the subject of estrogen, alpha estradiol, are you familiar with that substance or drug?

A. Yes, sir.

Q. In connection with your work, do you use a book called "Physician's Desk Reference, 1948"?

A. I have that on my desk; yes. [612]

Q. Just what is that?

A. Well, it is put out, or I believe it is put out, by the Year Book people. I am not sure about that now. But it is a general therapeutic index to practically all drugs manufactured in one certain year. You can find anything there from aspirin right on

(Testimony of Dr. Paul Edward Travis, M.D.)

up to penicillin. It includes all of the drugs that are manufactured.

Q. Did you look at that work before you came up here to court? A. Yes. I have it on my desk.

Q. And did you look at it with reference to alpha estradiol?

A. I knew that was going to come up. So I did; yes. [613]

* * *

Q. (By Mr. Elson): Coming to a half a milligram tablet of alpha estradiol, a dosage of two per day, in your opinion, would that dosage be dangerous to a female in that it might accelerate a cancer of the breast, cervix or uterus?

A. No, because we don't know that estrogen will stimulate a cancer of the breast, cervix or uterus.

Q. What do you mean when you say "we don't know it"?

A. I don't think it is even definitely proved.

Q. Is there an opinion that it may and an opinion the other way that it may not?

A. Absolutely. Like in any phase of medicine, there are always two opinions.

Q. Have you encountered any adverse results in patients who took alpha estradiol?

A. I had one patient who thought that, if two tablets per day did her good, she would take four and she produced uterine bleeding inside of three weeks. Upon cessation of the drug, the bleeding stopped.

Q. On that subject of uterine bleeding, do you

(Testimony of Dr. Paul Edward Travis, M.D.)

think, if a woman took enough alpha estradiol to cause uterine bleeding, that that would be dangerous to the woman?

A. No. It would simply indicate that she was taking too much and she should stop. [614]

Q. Has it been your experience that usually, when women start uterine bleeding, they come to the doctor anyway?

A. Absolutely. That brings them back in a rush.

Q. Dr. Macdonald stated here—do you know Dr. Macdonald?

A. Yes. He was a former professor of mine in the University of Southern California.

Q. Dr. Macdonald stated, in his opinion, such dosage might produce acceleration of the growth of a cancer and so on, and the danger that he associated with it, page 130, was, as a result of this bleeding—he said it is difficult to tell whether such bleeding is a result of the developing growth, malignant or otherwise, in the uterus, or whether it is simply due to a disturbance of the lining of the uterus, from the use of the hormone. Now, under such circumstances, do you consider that dangerous?

A. No. As a matter of fact, it is beneficial. If a patient comes in to you with uterine bleeding and if it doesn't cease, that is, if they are taking estrogen, if it doesn't cease upon removal, then you are definitely suspicious and maybe you do a curettement to see what is causing the bleeding. I think it is beneficial for the patient to come in.

(Testimony of Dr. Paul Edward Travis, M.D.)

Mr. Danielson: What is this thing you are going to do? [615]

The Witness: A curettement, which is a scraping of the lining of the womb to determine whether there is an over-development of the lining of the womb or whether there is cancer there.

Q. (By Mr. Elson): Doctor, coming to a tablet of alpha estradiol of .1 milligrams per tablet per day for a period of 10 days and thereafter one per day, in your opinion, would the taking of such a dosage of that quantity be dangerous to the individual? A. No.

Q. Do you consider that to be a large dose or a small dose?

A. It is a moderate dose. It is not small and it is not large.

Q. You are familiar with the dosules used for breast development, are you?

A. Do you mean creams, estrogen creams?

Q. Estrogen creams or something. A. Yes.

Q. With reference to count 3, Government's Exhibit 3, Menformon Dosules, I show you now the exhibit, consisting of the labeling, and ask you to read it. A. Yes.

Q. Doctor, have you ever used that product or a similar product, of similar strength? [616]

A. Yes, I have.

Q. And with what results?

A. I had excellent results in one case. In a couple of others they said they got good results but in one case it very definitely had a marked increase

(Testimony of Dr. Paul Edward Travis, M.D.)
in the size of the bust, following the administration
for about three months.

Q. Is it unusual in the practice of medicine for
a drug to be efficacious or appear to have therapeutic
value with one person and not have it with
another? A. That is the rule; yes.

Q. Have you read any of the literature on the
use of such dosules?

A. Yes. The French are great on that medicine.
As a matter of fact, I think they originated the
work and had the original cream, and they are very
keen on it and have reported numerous articles in
which they have gotten excellent results. I think
probably they are a little biased in reporting such
a high percentage of results but I do think you can
get results with a properly selected case.

Mr. Elson: You may cross-examine.

Cross-Examination

By Mr. Danielson:

Q. Doctor, I believe you testified you are now
practicing medicine here in Los Angeles?

A. A general practitioner; yes.

Q. In private practice? [617]

A. Yes, sir.

Q. How long have you been so practicing,
Doctor?

A. Since July 1, 1948.

Q. Roughly, one year? A. Roughly.

Q. Prior to that time you were with the Vet-
eran's Administration?

(Testimony of Dr. Paul Edward Travis, M.D.)

A. Yes; for two years.

Q. And prior to that you were an interne, is that correct? A. That is right.

Q. And you have had one year of general practice so far? A. That is right.

Q. Are you an urologist, Doctor?

A. Not as a specialist; no.

Q. In other words, you don't specialize in urology? A. Oh, no.

Q. Are you an endocrinologist, Doctor?

A. No; not as a specialist.

Q. Are you a gynecologist? A. No, sir.

Q. In other words, you are in the general practice? A. Everything from toenails to hair.

Q. What is your professional address? [618]

A. Huntington Park.

Q. I mean your office address?

A. 7310 Seville Avenue in Huntington Park.

Q. California? A. California.

Q. Are you acquainted, Doctor, with a doctor by the name of Charles Huggins, or with his work?

A. Yes; we studied that in medical school.

Q. Do you consider him to be an authority in his field, Doctor? A. Yes; he is.

Q. Are you acquainted personally or by reputation with Dr. Elmer Belt of Los Angeles?

A. By reputation.

Q. Do you consider him to be an authority in this field? A. Oh, yes.

Q. Are you personally acquainted with or by reputation with Dr. Norris J. Heckel?

(Testimony of Dr. Paul Edward Travis, M.D.)

A. No; I don't know him.

Q. Or Dr. Ian Macdonald in Los Angeles?

A. He was a professor of mine.

Q. Do you consider him to be an authority in his particular field? A. Yes. [619]

Q. In fact, he taught you a good deal of what you know, I presume? A. He surely did.

Q. Are you acquainted at all with Dr. Warren O. Nelson? A. No; I am not.

Q. Of the University of Iowa?

A. I don't happen to be.

Q. You attended the University of Iowa, did you not? A. Yes, but in another department.

Q. How old are you, Doctor? A. 28.

Q. You spoke of the male change of life or male menopause or climacteric and in so doing you mentioned that the symptoms would be comparable to the symptoms of the climacteric or menopause in the female.

A. Except for cessation of menses; yes.

Q. Just what are the primary findings or the phenomena associated with the change of life in a female? Are they not a cessation of ovulation?

A. We assume that to be the case; yes. We can't tell but we know that to be true because the menses cease.

Q. And with that an atrophy or shriveling or disuse of the ovary?

A. Yes. Actually, they don't shrivel. They remain the same size but they cease functioning. [620]

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. Together with a gradual cessation of the production of estrogen by the ovary?

A. That I don't know.

Q. Have you ever conducted any clinical research into this phenomenon?

A. No. I haven't.

Q. As to a male, if there were comparable symptoms or changes, wouldn't the testes take the place of the ovary? A. Roughly, yes.

Q. In other words, the testes would cease to produce their natural products? A. That is right.

Q. Which would be sperm and testosterone, is that not correct? A. Well, partly it is.

Q. Are not sperm produced by the testes?

A. Yes, but they are not necessarily diminished in later life.

Q. In other words, the testes do not change as do the ovaries?

A. They don't change in size and neither do the ovaries change in size.

Q. But the testes continue to produce sperm?

A. In some cases, in amazing quantities.

Q. But the ovary no longer produces the [621] ovum?

A. However, some investigators claim that it does.

Q. We are speaking of the general run of people. A. Yes; they are both similar.

Q. Doctor, what, if any, clinical or laboratory experience have you had in determining whether or

(Testimony of Dr. Paul Edward Travis, M.D.)

not the testes in a male past the age of say 50 continue to produce testosterone?

A. None whatsoever.

Q. Have you ever conducted any type of examination or analysis to determine what is the testosterone production of the glands of a male of that age?

A. No.

Q. You have had no experience along that line?

A. No; nor of a female on estrogen.

Q. Then, actually, how do you determine whether or not there is a deficiency of the male hormone in a male past that age?

A. Simply by subjective symptoms. In other words, you get the patient's story, and then, by trial and error, you use testosterone and, if they are relieved, you assume you have corrected a procedure or are using the correct procedure.

Q. You mentioned some symptoms. You mentioned loss of libido or diminution, loss of a sense of well-being, nervousness, irritability, that they don't sleep well and, "Doc, I just don't feel well." Those are the symptoms on which you [622] go, are they?

A. Some of the symptoms.

Q. Aren't some of those symptoms, likewise, the symptoms of fatigue or over-tiredness?

A. They can be symptoms of most anything.

Q. Tuberculosis?

A. Yes, and heart disease. They are general symptoms. They are not all present in all of these other diseases. You can pick out fatigue, which is certainly a symptom of many diseases. Nervousness

(Testimony of Dr. Paul Edward Travis, M.D.)

is a symptom of many other diseases. But they are not present in that same symptom complex. In other words, they are not all present at the same time.

Q. Are they all present at the same time in the instance of a male hormone deficiency?

A. Practically always; yes.

Q. But not invariably, apparently?

A. Oh, no. Nothing is invariable.

Q. Is that also true in symptoms such as flushes, sweats, chills, lack of sexual power, impaired memory, inability to concentrate on activities or a tendency to evade them, depression, general weakness and poor physical strength? Are they, likewise, a part of this symptom complex?

A. Yes; they can be.

Q. But they are not, necessarily? [623]

A. Not all the time; no.

Q. And, likewise, they are also symptoms found in the many other diseases to which you have just referred, is that not correct?

A. Some of them are; yes.

Q. As a matter of fact, isn't impotence the same thing you referred to as loss of libido?

A. It is usually a part of the picture.

Q. Is that what you had reference to when you mentioned a loss of libido?

A. No.

Q. What did you refer to?

A. Loss of libido can be concerned with a sexual drive in other fields besides ability to have sexual intercourse.

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. But would you consider impotence as being one of these——

A. A part of loss of libido; yes.

Q. You say that impotence can be overcome by male sex hormones? A. Yes; it can.

Q. Do you know whether there are other causes of impotence besides a deficiency of the male sex hormone?

A. One of the biggest of them is psychogenic and, if a person has lost his impotence by virtue of psychogenesis, a male sex hormone would not give it back to him. [624]

Q. What would give it back to him?

A. It might through suggestion, which makes it a therapeutic drug.

Q. Of course, a sugar pill would perform the same function, wouldn't it, if the man believed in its efficacy?

A. It is a marvelous drug sometimes.

Q. But the cause of the renewed potency would be psychological rather than the testosterone in that case? A. What do you mean by the cause?

Q. What would give him back his potency?

A. The drug through suggestion, because it is just as effective mentally as physically but——

Q. But a sugar pill would, likewise, wouldn't it?

A. Yes, sir.

* * *

The Witness: Of course, as a rule, men seeking a cure for impotency don't take sugar pills.

Q. (By Mr. Danielson): But in psychogenic cases one has worked the same as the other one?

(Testimony of Dr. Paul Edward Travis, M.D.)

A. Yes. We are interested in helping the patient and, if the patient gets relief, that is what we are after.

Q. But, so far as you are concerned, the sugar pill would work as well as the testosterone?

A. That is right. [625]

Q. It is the fact that the doctor is giving something that overcomes that?

A. Yes; plus massive doses of reassurance in many cases.

Q. Doctor, is it not true that the general indication for sex hormone therapy is to replace something that nature either has failed to provide or no longer provides in adequate quantity?

A. That is right. All hormone therapy is replacement therapy.

Q. Then, as a condition precedent to any bona fides, would be a shortage or a deficiency of the hormone?

A. Will you state that again, please?

Q. A condition which is prerequisite to any need for hormone therapy is a deficiency in the hormone, is that not correct?

A. Mentally or physically; yes.

Q. You have to be short of hormones before you need hormones in that case?

A. Or think you are short of them.

Q. We are talking about real factors rather than psychological at the moment.

A. You can't divorce the two. You have got to think of them together.

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. Doctor, you have stated, however, that replacement [626] therapy is the keystone of hormone therapy? A. Absolutely.

Q. And in making up for something which Nature is not now providing?

A. In sufficient quantity.

Q. In other words, in your testimony as to the Menformon Dosules or estrogenic ointment for cosmetic development of the bust, you stated that in a properly selected case you could expect favorable results. Just what do you mean by a properly selected case, Doctor?

A. A female past puberty. In other words, you can't take a young girl, because she hasn't even come into puberty. And we know that during puberty is when the female hormones start to increase. You have to take a female past puberty who has definitely shown her estrogen level is not going to increase to the point where she is going to develop the bust.

Q. That is a hypogonad, is it not?

A. Or just a lack of estrogens. You take a woman past say 18 or 20 and you know that they are not going to get any further development in bust through their own natural hormonal development. You are going to have to supply it.

Q. This is a person whom you have determined will not get further development through her own natural supply of hormones? [627]

A. Yes, sir.

Q. She is deficient in hormones, is she not?

(Testimony of Dr. Paul Edward Travis, M.D.)

A. Yes; she is.

Q. That is not just any normal woman walking down the street, is it? A. No.

Q. When you qualified your answer by saying "in a properly selected case," you were referring only to this woman who had a deficiency in hormones, is that not correct?

A. No. What I meant was a woman past puberty.

Q. And, likewise, deficient in the hormone, is that not correct, if she has a very small bust?

A. She is usually deficient in that.

Q. Will you answer my question? You were referring to a woman who is deficient in the hormones, is that not correct?

A. If she has a flat bust and she is deficient in hormones. That is what I mean.

Q. And if she is deficient in hormones?

A. Yes.

Q. Doctor, have you ever removed a prostate?

A. No.

Q. Have you ever treated anyone for carcinoma of the prostate?

A. Yes, I have. I have a patient under treatment now. [628]

Q. Are you using sex hormone therapy?

A. Yes; stilbestrol.

Q. That is the female hormone, is it not?

A. Yes; that is right.

Q. Would you feel safe in putting this man on testosterone at this time?

(Testimony of Dr. Paul Edward Travis, M.D.)

A. I wouldn't hesitate; no.

Q. Have you done so?

A. No. But I wouldn't hesitate if it was necessary to relieve certain symptoms. [629]

Q. (By Mr. Danielson): Have you referred this patient to an urologist, by any chance, Doctor?

A. Yes, and the patient has come back.

Q. Now, you likewise stated, Doctor, that a busy general practitioner would not have time to conduct a very thorough physical examination, the type of physical examination which was described to you by Mr. Elson in the course of your examination?

A. That is right. It would take you roughly two hours.

Q. What is the usual examination for determining the presence of prostatic cancer?

A. You mean if the patient comes in to you?

Q. Yes, the ordinary, routine examination, what is that?

A. Well, if I suspect cancer of the prostate, I simply refer the patient to an urologist, but usually if you are just going through a routine examination, you do a rectal examination.

Q. A rectal examination, is it usual?

A. That is right.

Q. That is the one you refer to, is it not, as taking about 30 seconds? A. That is right.

Q. In other words, in about 30 seconds, the doctor can make the usual examination for cancer of the prostate? [630] A. Absolutely.

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. Don't you think that a very busy practitioner would not have time to do that, where a patient came in to a doctor and gave him a 30-second examination?

A. You usually do that, but you certainly do not take gastro-intestinal X-rays and make all the other special time-consuming examinations that the doctor mentioned.

Q. When you make your rectal examination and you find something which gives you suspicion of cancer, did you not just testify that you refer that man, then, to an urologist?

A. That is right. He has fewer patients and takes more time.

Q. And is more specialized?

A. That is right.

Q. And who conducts probably more thorough examinations on that particular point?

A. He follows the patient up, that is correct.

Q. In other words, as a general practitioner, you make this quick, the rectal examination. If you have, then, reason to suspect cancer, then you refer them to the specialist for the more detailed, more technical examination?

A. That is certainly right.

Q. Now, Doctor, you were asked as to testimony appearing on page 176 of our transcript, how is male hormone deficiency in any person determined—I am accenting the word [631] “determined” as opposed to trial and error or guesswork.

“A. Determined by first a careful history.” Is

(Testimony of Dr. Paul Edward Travis, M.D.)
that an unusual situation? You always take the history of your patients, do you not, Doctor?

A. Oh, yes.

Q. "2. A careful physical examination." When a patient comes to you and says, "Doc, I just don't feel well," you make a physical examination, do you not?

A. I start in there to go from head to toe, that is correct.

Q. And then, "3. There are some laboratory tests that will aid in diagnosis such as the estimation of the 17 ketosteroids in the urine." That is a specialized test, is it not?

A. Yes, it is.

Q. Now, Doctor, you testified, however, on that point that a general practitioner would not have the time to perform these tests, because they are all specialized tests. You are really only referring to the one relative to the 17 ketosteroids, weren't you, Doctor?

A. That, plus a cystoscope examination would be considered specialized.

Q. By taking their history, plus the physical examination, you don't feel that they are specialized for the average practitioner, do you? [632]

A. That is right. You do those every day.

Q. Doctor, have you ever performed a biopsy on a patient, on the prostate?

A. No, sir, I haven't.

Q. But I believe you testified that you were not capable of performing one or at least not prepared to perform one?

A. That is right. I don't believe any general

(Testimony of Dr. Paul Edward Travis, M.D.)

practitioner is prepared to do a biopsy of the prostate in his office.

Q. And an urologist could perform one?

A. Yes, I imagine so, but I still think he would take the patient to the hospital.

Q. But he can perform it in the hospital or elsewhere? A. Oh, yes, he is capable of it.

Q. And did you not testify that when you suspect cancer of the prostate, you refer a man to an urologist? A. That is right.

Q. For further examination?

A. That is right.

Q. Now, as to cancer of the prostate, you testified that you can't diagnose it when it is incipient, yet, you also testified, Doctor, that you have diagnosed at least one cancer of the prostate, in treating a man. A. That is right. [633]

Q. About how large was it?

A. The cancer of the prostate?

Q. The cancer, yes.

A. It had consumed an entire lobe or half of the prostate.

Q. And you are treating it? A. Yes.

Q. Do you feel that a cancer can be diagnosed at an early stage so that it can be subjected to some beneficial treatment?

A. Even this one was at a far-advanced stage. Yet, he is getting benefit, very definitely, even though it was a far-advanced cancer when he came to me.

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. If a cancer is diagnosed at an early enough stage, the earlier the diagnosis, the better the treatment, is that the theory on them?

A. That certainly is, especially in cancers.

Q. And the smaller you can catch them, the better off you are?

A. Well, size really does not have anything to do with it. It is its stage of growth, whether or not it is spread beyond its boundaries into other organs or things like that.

Q. So long as it is confined to its original situs and is fairly reasonably small, you can give some beneficial therapy? [624]

A. Well, size doesn't have anything to do with it, but as long as you say early cancer, when it is early, before it is spread to other organs, then is the time to get it and take it out.

Q. Would that be more or less the status of the one you diagnosed?

A. No. My man came to me with far-advanced cancer, with metastasis throughout his body.

Q. But they can be diagnosed before that spread, before that metastasis? A. Yes.

Q. And that would be considered in its early stage? A. Not too early.

Q. But fairly early? A. Yes.

Q. You have testified that there is quite a difference in opinion on the effect of testosterone on cancer of the prostate. I believe you testified that some doctors even say that testosterone will inhibit cancer of the prostate, is that right? A. That is right.

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. Will you state for me any such authority?

A. There was an article in The New England Journal of Medicine two years ago, and it was a symposium on male hormone and its effect on cancer of the prostate. I read it down at [635] Phoenix. The New England Journal of Medicine is, as you know, a journal conducted by the Massachusetts General Hospital, and they have many of the world's best authorities in various fields at that hospital. They had a symposium on the effect of male hormones on the prostate gland. And they had the consensus of opinion. They were very much divided.

Q. Would you say that this article contends that testosterone inhibits the growth of cancer of the prostate?

A. One man worked with, I believe it was monkeys, and had found that very, very large doses of testosterone had inhibited artificially produced cancer of the prostate.

Q. That is the gist of this article to which you are referring?

A. No. That was one of the points. It was a pro and con article, a symposium.

Q. That was one man's opinion based upon this experience with a monkey, in other words, is that correct?

A. That is right.

Q. Rather than the gist of the article that you have referred to?

A. Well, the gist of the article was a symposium, with pro and con opinions.

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. It was a group of various, varying opinions, in other words?

A. That is right. Everyone seemed to have a different [636] opinion.

Q. And the one to which you referred as saying that it inhibited the growth of the cancer of the prostate referred to this one man's experience with a monkey?

A. With a group of monkeys, yes, he ran a series.

Q. One man's experience with a group of monkeys.

To get back to the cosmetic effect on the busts of women, for one moment, is it not true, Doctor, that there are at least a few women, I would not say many women, who have flat busts and yet are not deficient in female hormone? A. Probably so.

Q. As a matter of fact, that is true, is it not, Doctor? A. It probably is, yes.

Q. Are you acquainted with Dr. Samuel Glass or are you acquainted with him by reputation?

A. I have read some of his articles, yes.

Q. Do you consider him to be an authority in this field?

A. I believe he is considered to be an authority, yes.

Q. I wish to understand one of your statements a little more fully. In your testimony, you stated in referring to a biopsy of the prostate, that if a such a thing were suggested to a patient, he probably would not come back again?

A. The general patient coming to a general prac-

(Testimony of Dr. Paul Edward Travis, M.D.)

itioner wanting relief from certain symptoms, if you start out mentioning [637] to him a surgical procedure, they begin to think that your real intentions are not all that they should be and they usually don't come back.

Q. But, as a matter of fact, there may be several things that a doctor may have to tell a patient from time to time which will either scare or disappoint at least a patient, isn't that true?

A. Oh, certainly, but you usually don't start out that way.

Q. In good professional practice, though, you would start and have to carry these things out, whether he liked them or not, wouldn't you?

A. We try not to start out that way, though.

Q. But, if a treatment were indicated, you would have to in the interest of your patient carry out whatever step was necessary?

A. You tell the patient that that step is necessary, but you don't carry it out, unless they consent.

Q. Sure, but nevertheless if a piece of surgery is necessary, regardless of whether the patient likes it or not, you are going to tell him it is necessary, aren't you?

A. That is right, but I don't consider routine biopsies of the prostate a necessary piece of surgery in any patient.

Q. Nevertheless, if you had a suspicion of cancer of the prostate, referred your patient to the urologist and [638] diagnosis became so obscure that it

(Testimony of Dr. Paul Edward Travis, M.D.)
was necessary to perform one, you would not hesitate to advise a biopsy?

A. No. If I suspected cancer of the prostate, I would certainly refer the patient to the urologist who would advise the biopsy.

Q. Regardless of whether the patient liked the idea, you would still tell him it was necessary?

A. That is right.

Q. In this case of the cancer of the prostate, you said in treating it, you used stilbestrol?

A. Dyethyl-stilbestrol.

Q. Why have you used stilbestrol on this patient?

A. Because it alleviates symptoms.

Q. As a matter of fact, isn't it because it tends to counteract the influence of testosterone?

A. I don't know, but it just relieves symptoms.

Q. But, as a matter of fact, isn't it true that the literature holds at least that the stilbestrol tends to counteract or offset the action of the testosterone?

* * *

A. I will say I don't know.

Q. You don't know? [639]

A. That is right.

Mr. Danielson: Very good. Thank you.

Q. Is it not true, in treatment of cancer of the prostate, that castration is frequently resorted to?

A. I have never in my experience had that happen—had to do that, no, sir.

Q. You have never done that? A. No, sir.

Q. Are you familiar with good medical practice along with treatment of cancer of the prostate?

(Testimony of Dr. Paul Edward Travis, M.D.)

A. Yes. I believe they are no longer doing castration in general out in private practice. That certainly is experimental. I believe Huggins in about 1941 started a series of cases in which he did orchietomies, or castrations.

Q. Yes.

A. But I believe they have almost stopped doing that, now, because of the terrific psychogenic trauma that was produced, and now they are simply giving large doses, very large doses of dyethyl-stilbestrol.

Q. In other words, they use the stilbestrol to take the place of the castration, is that correct?

A. Apparently, yes.

Q. If you were to hear Dr. Elmer Belt testify that castration is practiced for that purpose, would that tend to change your opinion? [640]

A. Certainly, if in his practice he does that, that is fine. I would not certainly do it in mine.

Q. That would change your opinion as to whether or not it was still being practiced?

A. Still being practiced in office clinics.

Q. And if you heard Dr. Huggins testify to the same effect, that the same practice was still being practiced in 1949, would that change your opinion as to whether it was still in general practice?

A. No. Dr. Huggins happens to be connected with the University Hospital, in which he can, very frankly, get away with experiments.

Q. Now, I asked you a question.

A. No. It would not change my opinion.

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. Then, you would still say that castration is not in general practice today?

A. That is right.

Q. Even though Dr. Belt and Dr. Huggins gave testimony to the contrary?

A. That is right, because I know other urologists who would testify to the contrary.

Q. Have you ever conducted any analysis to determine definitely whether males over the age of say 50, this climacteric age to which you refer, do or do not produce testosterone? [641]

A. No, sir, I haven't.

Q. Now, as to sterility, you stated on direct examination that at 45 it is too late for a male to have children. You did not exactly mean that, did you, Doctor?

A. No. What I meant was that he usually doesn't prefer children at that age.

Q. By the way, you don't mean that a man is sterile at 45, whether he likes it or not, do you?

A. No, no. Many of them remain fertile at 86. The newspapers said so, anyway.

Q. And you also stated that the question of fertility has never come up in your practice, that is in men over the age of 45? A. That is right.

Q. Have you had very extensive practice in the field of sterility, Doctor?

A. I have conducted sperm counts and basal temperatures for couples desiring children, yes.

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. Have you had a very extensive practice along that line?

A. About a dozen patients—couples, a dozen couples.

Q. As to those symptoms of the male menopause, again I don't wish to enumerate them, unless you wish.

A. I remember them.

Q. I think we all have them in mind. What did people [642] use for the purpose of treating those symptoms prior to the advance of testosterone, Doctor?

A. Probably sugar pills.

Q. And that has not been much over ten years ago, since testosterone became available?

A. Ten to 15 years.

Q. Recently in medical experience?

A. That is true.

Q. Sugar pills would have been the treatment prior to that time?

A. Or Cascara, yes.

Q. Now, you mentioned in response to a question that you thought, as to the effect that testosterone would have sterility, that apparently in effect there were three schools of thought, some said it would produce sterility, some said it would not do anything in particular and others said it would increase fertility?

A. That is right.

Q. What is your opinion on the basis of your training, experience and study?

A. Well, as I say, I have never examined a patient for sterility or fertility.

Q. You do not personally have an opinion as to that, as yet, is that correct?

(Testimony of Dr. Paul Edward Travis, M.D.)

A. Not for patients who wish relief for male climacteric [643] symptoms. I had one couple who desired a child and the husband had been a veteran in the South Pacific about five years and when he came back he was a little bit impotent and he also had very low sluggish sperm count, and upon administration of testosterone propionate, which is another form of testosterone (you administer that by injection form twice weekly), the wife conceived and his sperm count subsequently became elevated and the sperm count became more motile, the sperms became more motile.

Q. Was that at Phoenix, Doctor?

A. No. This has been in my private practice.

Q. Now, do you have an opinion, Doctor, as to whether or not the use of testosterone will inhibit the generation of sperm or will increase the generation of sperm or will have no effect upon it?

A. I think it depends upon the age of the patient.

Q. You have no definite opinion on that, then, is that correct?

A. That is right, just from what I have observed in my own practice.

Q. Now, to get back to the uterine bleeding, the use of the alpha estradiol. Have you ever used these 5 milligram tablets of alpha estradiol on anyone, Doctor?

A. No. I prefer another preparation. I just happen to use another preparation similar to it. [644]

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. You have not used this particular preparation?
A. No.

Q. But you have used a similar one, though, in your therapy, in your practice?

A. Oh, yes, many times.

Mr. Elson: Just a minute, counsel. I think you said 5 milligrams.

Mr. Danielson: .5 milligrams. I am sorry. Correct it to .5 milligrams.

Q. Is that the instance in which you mentioned producing uterine bleeding in three weeks time?

A. That is right.

Q. And I believe you stated by the patient's own volition the dosage was up to four tablets a day?

A. Yes. That was a Premarin, a preparation called Premarin.

Q. What is the concentration of that?

A. There are four concentrations put out by Ahert-MeKenna Company.

Q. What dosage was she taking?

A. She was taking 1.25 milligrams capsule nightly, which they put out, a 1.25 milligram capsule. She happened to be taking two of the .625, which is the same thing, and she doubled her dose just like many people think if two is going to do you good, four will do you better, and she commenced uterine [645] bleeding in three weeks.

Q. What it boiled down to in gross, she was taking 1.25 milligrams?

A. She was taking $2\frac{1}{2}$ milligrams.

Q. $2\frac{1}{2}$?

(Testimony of Dr. Paul Edward Travis, M.D.)

A. Yes, and she was taking four of the .625.

Q. And this daily produced the uterine bleeding?

A. In three weeks, yes.

Q. I understood you to say that this was sometimes a beneficial result, this uterine bleeding, indirectly?

A. Beneficial result because the patient returns to you. They are more worried.

Q. In other words, you have more business then, is that it?

A. No. You can catch something early that might be dangerous, such as cancer.

Q. And how do you detect that?

A. By this curettement.

Q. What does that consist of, Doctor, the curettement?

A. First of all, if the patient is on a female estrogen, you are going to take it off of it and see if her bleeding stops.

Q. Surely.

A. If it doesn't stop, then you have to go ahead and determine why she continues to bleed, and one of the simplest [646] methods is simply to scrape out a lining of the womb and examine the cells in the lining of the womb microscopically. That will tell you whether you are dealing with a hyperplasia, with excessive amount of lining of the womb, or whether you are dealing with a malignant process such as cancer.

Q. And that is removed?

A. You do that in excessive bleeding.

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. And you do that, then, in order to determine what is the persistent bleeding of the patient?

A. If just upon removal of the female estrogen, she doesn't cease to bleed.

Q. In many of those cases, apparently you do not actually find cancer, then, is that correct?

A. That is right.

Q. And in those cases the surgery has been necessitated for no good reason, has it, Doctor?

A. It certainly relieved yourself and the patient, if she doesn't have cancer.

Q. What is that?

A. You have relieved yourself and the patient that she does not have cancer. Of course that is what brings them in to you, she is worried about cancer. They have already read articles in magazines that uterine bleeding is one of the cardinal signs of cancer of the womb. And if upon cessation of the female hormones, they don't cease bleeding, the woman [647] soon comes in to see you and inquires about whether or not she has cancer. And to put her completely at rest, you must do a curettement.

Q. (By Mr. Danielson): But, in the cases in which there was no cancer found upon this curettement, the surgery——

The Witness: Then usually they stop——

Mr. Danielson: May I ask the question? In other words, in these cases in which you find no cancer, the surgery has been more or less unnecessary, hasn't it?

A. No. You find something else that causes

(Testimony of Dr. Paul Edward Travis, M.D.)

bleeding, such as a polyp or fibroid or a paraplasic due to some other causes.

Q. Are you familiar at all with the work of Dr. Robert A. Kimbrough, an M.D.?

A. No, I am not.

Q. And Dr. S. Leon Israel, M.D. of Philadelphia?

A. No, I am not.

Q. And have you, by any chance, read an article entitled The Use and Abuse of Estrogen, appearing in the Journal of the American Medical Association, December 25, 1948?

A. No, sir, I haven't read that article.

Q. I would like to ask you a question there. On page 7 of that article, there is this statement:

"The unfortunate faculty of estrogen of inducing uterine bleeding in the postmenopausal woman is indirectly responsible [648] for many instances of neglected carcinoma of the uterus." Do you agree with that statement, Doctor?

A. No, I don't, because a woman bleeding from the womb will come in to you and you will be able to make a diagnosis. If you are a conscientious practitioner, you will withdraw the drug from use and if she does not cease to bleed, then you will investigate the bleeding.

Q. Supposing she buys this drug on being under your supervision, then, Doctor?

A. Then she starts to bleed, then she comes in to us.

Q. It will still cause the bleeding?

(Testimony of Dr. Paul Edward Travis, M.D.)

A. Oh, absolutely. Then they come in to you and you start from there.

Q. And it is true, is it not, sometimes the uterine bleeding is brought about by just the use of the hormone?

A. Oh, yes, in many cases uterine bleeding may be produced by the estrogen.

Q. Then, if any person developed uterine bleeding and attributed it to the use of the hormone, they would probably come in to have an examination made, then, would they not?

A. Well, what they probably would to would be to stop the hormone and if the bleeding continued, then they would become worried and seek medical advice.

Q. On the basis strictly of your familiarity with the use of these products, Doctor, would you advise one of such [649] patients, either a woman of this period to which we have just referred or a man in this male climacteric to which we have referred, to take such amounts of these hormones as he might wish, without the continued advice of the doctor?

A. They are certainly harmless and in prescribed doses they are perfectly all right, yes.

Q. And in non-prescribed dosages, to diagnose himself and buy his own, or her own amount of hormone as he or she wishes, would you advise that to any of these groups?

Mr. Elson: He is talking about something that is not in issue in this case, about no prescribed dosages.

(Testimony of Dr. Paul Edward Travis, M.D.)
The labeling of goods says dosage so much a day.
Don't you think we had better confine it to that?

Mr. Danielson: The 25 milligrams per day for males, 25 milligram tablets, two or three for males?

A. That is perfectly all right.

Q. Just go ahead and diagnose themselves and use them at will, is that correct?

A. Well, people do.

Q. I am asking you what you recommend, not what people do. Do you recommend that?

A. Do you mean if the patient comes in to me and asks me?

Q. No. Just any person.

A. I see no harm in it. [650]

Mr. Danielson: Very well. No further questions.

Re-Direct Examination

By Mr. Elson:

Q. Mr. Danielson asked you if in substance, you were informed that Dr. Huggins and Dr. Belt advised that castration was a present-day practice in connection with cancer of the prostate, would your opinion be changed in that way? Now, I will ask you if you were told that Dr. Heckel stated in substance, "However, men are castrated every day for the purpose of inhibiting the growth of cancer of the prostate, although not as many men are castrated as they were five years ago," would you be inclined to agree with that statement?

A. That is what I stated, yes.

Mr. Elson: That is all.

* * *

DR. WILLIAM A. SWIM

called as a witness by and on behalf of the defendants, having been first duly sworn, was examined and testified as follows:

The Clerk: Your full name?

A. William A. Swim. [651]

Direct Examination

By Mr. Elson:

Q. Dr. Swim, you are a doctor of medicine?

A. I am.

Q. Will you please state the schools that you attended?

A. I attended the University of Chicago, undergraduate, Rush Medical College.

Q. And did you graduate from Rush Medical College? A. Yes, I did.

Q. And was it from that institution that you got your M.D. degree? A. It was. [652]

Q. In what year? A. 1915.

Q. And then, thereafter, were you associated with any institutions, hospitals or the like?

A. Yes.

Q. Will you state what they were?

A. Well, I had an internship at Milwaukee Sanitarium for mental and nervous diseases, a period of one year at Los Angeles General Hospital, and the New Haven Hospital connected with Yale for a period of about seven months.

(Testimony of Dr. William A. Swim.)

Q. And you were in World War I for a time, were you? A. Yes, I was.

Q. And when did you come to Los Angeles?

A. In 1915.

Q. And when did you commence the practice of medicine in Los Angeles? A. In 1918.

Q. And was it in any particular branch of medicine, or what?

A. Yes. I have practiced internal medicine since then.

Q. Will you describe what internal medicine is?

A. Well, internal medicine consists of diagnosis and the treatment of non-surgical diseases, non-obstetrical.

Q. Are you connected with any state boards at the [653] present time?

A. Not at the present time.

Q. Have you ever been connected with any?

A. Yes.

Q. Will you state what it was?

A. I was a member of the Board of Medical Examiners for four years.

Q. Of this state? A. Yes.

Q. Now, Doctor, if an individual comes to you, say a male in middle life, and complains of nervousness, flushes, sweats, chills, general weakness, lack of physical strength, impaired memory, inability to concentrate on activities and a tendency to evade them, not necessarily all of those symptoms, what is your practice in dealing with that patient and his symptoms?

(Testimony of Dr. William A. Swim.)

A. Well, I take a general history of the present illness and the patient's past illnesses. I make a physical examination, including the head and neck and chest and abdomen, the prostate and rectum, the reflexes, the general appearance of the skin, and if I find no evidence of any constitutional disease of a specific nature, I prescribe testosterone or administer it.

Q. You mean you inject it? A. Yes. [654]

Q. Is it your usual practice to inject it rather than to prescribe it in tablet form?

A. I usually inject it.

Q. And have you done so on one or on many occasions? A. On many occasions.

Q. Over the period of practice that you have been here, since there has been testosterone?

A. Since there has been testosterone, with ever increasing number of cases.

Q. The testosterone has been available, let us say, in commercial quantities, during the past ten years or so, hasn't it? A. I believe so, yes.

Q. Now, on many of those occasions, have you found, after having administered testosterone, that the person's symptoms appeared to be relieved?

A. On many occasions, yes.

Q. On any occasion on which you have ever administered testosterone to a person, have you ever encountered what you considered were adverse results? A. Never.

Q. You understand the meaning of male climacteric? A. I think I do.

Q. And what do you associate that term with?

A. With a diminution of the secretion of the interstitial [655] cells of the testicle.

Q. And does that occur with young men, men in middle age or in old men?

A. Usually in a man around 50.

Q. And those men complain of what symptoms, usually?

A. They complain of fatigue, lack of concentration, loss of memory, loss of appetite, sleeplessness, sometimes a sense of heat in the body, and profuse perspiration.

Q. The other day one of the witnesses for the government stated as follows (pages 39 to 41) that: Assuming a man to be 50 years of age, who complains of flushes, sweats, extreme nervousness, inability to concentrate, nocturia, and he goes to his doctor who is a general practitioner, no evidence of cancer of the prostate is diagnosed, he does not believe that the doctor would prescribe testosterone for a period of time, and wait and see whether the symptoms were relieved, and before he could answer that the practitioner would prescribe it, he would have to know more of what the examination consisted and what the urologist may have done by way of examination, if the urologist report was that he had palpated the prostate and performed a biopsy and found no evidence of cancer of the prostate, and no enlargement of the prostate and laboratory tests showed that there was a marked decrease in the secretion of testosterone, even then, in his opinion, testosterone would not be prescribed

(Testimony of Dr. William A. Swim.)

by [656] the man's doctor unless there was further evidence of the male climacteric.

Now then, assuming that that same individual came to you and complained to you, being a man of 50 years of age, would you follow through the elaborate procedure described by that doctor?

A. No, sir.

Q. What would you do?

A. Just what I have already indicated, I would make a physical examination and a rectal examination and if I found no tumor mass in the prostate, I would prescribe testosterone.

Q. By the way, do you believe that it is possible to diagnose or detect an incipient cancer of the prostate?

A. It is not possible.

Q. What size does a cancer of the prostate have to be, before you are able to find it by palpation?

A. Well, I would say the size of a walnut.

Q. A small or large walnut?

A. A medium sized walnut.

Q. In the practice of medicine—oh, by the way, with this individual that we have just talked about on that elaborate test that this other doctor mentioned, what in your opinion would be the attitude of the average patient if such procedure were suggested for the relief of those symptoms? [657]

A. I think he would not follow through. He would probably refuse to go through the procedure, unless he felt definitely that a diagnosis of some malignancy had been made.

Q. And thereupon either go to some other doctor

(Testimony of Dr. William A. Swim.)

who would do it without that procedure, or go unrelieved? A. Yes, I think so.

Q. Now, in the practice of medicine, do you consider that medical work is, in the great majority of instances, specific or is it hypothetical?

A. In many instances, it is hypothetical, in the majority of instances.

Q. Are there many specifics, in medicine?

A. Not many.

Q. Specific treatment for a specific condition which you know is going to produce that result, there is no question of it? A. Not many.

Q. From your experience, do you consider that enlargement of the prostate as a rule indicates a cancerous condition? A. No.

Q. What do you consider that it indicates, as a rule?

A. Benign hypertrophy of the prostate.

Q. And what is that? [658]

A. Which is simply an overgrowth of the prostatic tissue. Some call it a tumor.

Q. I don't think I asked you this, but if I did I am going to ask it again anyway: In your practice, approximately how often, how many times per week do you prescribe testosterone, just approximately? A. Oh, once a week probably.

Q. Have you ever injected testosterone propionate into doctors of medicine? A. Yes.

Q. On one or more than one occasion?

A. On more than one occasion.

(Testimony of Dr. William A. Swim.)

Q. And prior to that injection, did you conduct a rectal examination? A. No.

Q. Did the doctors ask for it? A. No.

Q. Now, there was a doctor the other day who testified for the prosecution, Dr. Heckel, page 173, that in his opinion men in middle life do not generally have a deficiency of male sex hormone. Do you share the opinion of that doctor?

A. I do not.

Q. Will you state why?

A. Well, I think men of middle age do have a deficiency, [659] that is, their concentration of their hormone is below its maximum.

Q. Take this individual in whom you inject testosterone propionate and he comes back in three to four weeks or something like that and the symptoms have disappeared or have been relieved, what conclusion would you come to?

A. That I had supplied him with a hormone that he had been deficient in.

Q. And if that man came back and the symptoms were not relieved, what would you do?

A. I might change the dose. I would change the dose.

Q. And if that kept on and no result was accomplished, would you try something else?

A. Yes, I would.

Q. As a matter of fact, in the practice of medicine, it is to a large extent trial and error, is it not?

A. It is, yes.

Q. Now, Doctor, Dr. Heckel stated the other

(Testimony of Dr. William A. Swim.)

day (page 176) that a male hormone deficiency is determined, first, by a careful history; second, a careful physical examination and, third, laboratory tests to aid in diagnosis, such as the estimation of 17 ketosteroids in the urine, also such deficiency is determined by the estimation of the excretion of gonadotropins also in the urine. Is it your practice to conduct such a test to determine whether a man has a hormone [660] deficiency, prior to administering testosterone to him?

A. No. It is not.

Q. By the way, in your practice, are you aware of any other doctors in this locality that conform to such tests? A. I am not aware of any.

Q. Now, also, Dr. Heckel stated (I don't find the page, but I remember it distinctly) that in the case of an early or incipient cancer of the prostate, it might require a biopsy of the prostate to determine its existence. Have you had any experiences where a biopsy of the prostate has been performed to determine whether or not a cancer of the prostate existed? A. No. I have not.

Q. And, by the way, if a biopsy of the prostate was made, would that necessarily and conclusively determine that there was a cancer there?

A. It would not necessarily.

Q. Wouldn't it be possible that the tissue that was taken out from the prostate would not be part of the tissue that was infected, if it were infected?

A. That is true.

(Testimony of Dr. William A. Swim.)

Q. In your practice, approximately how often do you encounter a cancer of the prostate?

A. Very seldom.

Q. And by that what do you mean? [661]

A. I think I have seen three in my practice.

Q. Now, the other day this same doctor, Dr. Heckel, stated, on page 186, as to a patient coming to a general practitioner, complaining of the several symptoms, nervousness, fatigue, loss of memory, inability to concentrate and so on, such as we have discussed, in Dr. Heckel's opinion the practitioner would make a careful examination of the patient to see if he could find out what is producing those symptoms, he would conduct a complete physical examination from head to foot, he would examine the urine to see whether there was any sugar in it, which might give him a clue that this patient might have diabetes, which would produce such symptoms. If there were no sugar, then he would look at the urine to see whether there was albumin in the urine or casts in the urine, which would indicate that the patient, in all probability, would be suffering from Bright's Disease or some kidney disturbance. If nothing turned up, then he would take the patient's blood pressure and if that was normal, there might be some indication that the patient had a gastro-intestinal disturbance and an X-ray picture of the stomach or an X-ray picture of the colon would be taken or a basal metabolic test made to discover whether or not he had some disturbance of his thyroid. If such a doctor found

(Testimony of Dr. William A. Swim.)

nothing suspicious as a result of such a complete examination, he might, but he shouldn't suggest testosterone [662] to the man for a period of four to six weeks, to see if those symptoms were relieved.

Do you agree or do you disagree with the opinion of Dr. Heckel as to what the practitioner would do?

A. I disagree.

Q. Have you ever done such a thing prior to administering testosterone for those symptoms?

A. No.

Q. Do you know of any doctor in your experience who has done so, other than in the experimental field?

A. No.

Q. Now, have you had occasion to review the literature on the subject of testosterone in its relation to cancer of the prostate?

A. I have read some articles, yes.

Q. Now then, as a result of your reading, as a result of your experience in the practice of medicine and as a result of your contacts with other doctors and meetings with them, in your opinion, will testosterone propionate at 25 to 50 milligrams a day accelerate the growth of an incipient carcinoma of the prostate?

A. No.

Q. In your opinion, is such a quantity of testosterone taken orally, daily, dangerous?

A. No. [663]

Q. Now, testosterone is a natural product, isn't it, in the male?

A. Yes.

Q. Is it possible for you, on the basis of your experience, to tell how much testosterone over and

(Testimony of Dr. William A. Swim.)

above that which an individual produces, would be necessary to accelerate the growth of any kind of a cancer? A. No.

Q. Why is that? Why is that?

A. Well, in the first place, cancer has no particular line of progress. It is the one lawless thing that we have in human pathology. A cancer may lay dormant for many, many years. It may flare up, without any apparent provocation and grow rapidly and destroy life in a very short time.

I had one case that was turned over to me to give morphine, for palliative treatment, during her last months after she had surgery and had X-ray treatment and had been given up as a possibility of a saving. I gave her a quarter of morphine, about one a day. Three years after that time, a cancer expert could find no cancer in her and she died six years later.

Another case of cancer of the breast, who had some other complications that contra-indicated surgery at the time, developed metastasis so rapidly without any benefit, without any treatment with testosterone or any other hormone, without [664] any specific hormonal treatment, that she was inoperable by the time these complications had been corrected.

Q. That reminds me, two or three of the other doctors for the government here have spoken of cancer of the prostate and cancer of the breast following a usual pattern of growth. In your ex-

(Testimony of Dr. William A. Swim.)

perience, have you ever found cancers of any kind to follow a usual pattern? A. No.

Q. Will you explain that?

A. Well, they are just simply lawless. One never can tell. We do not understand the pathology of cancer and we do not have any orderly procedure. We just simply cannot put the course of cancer down like we can the course of infections, infectious diseases, because they vary too much from any average, so as to make what we might call the average worthless to follow.

Q. If cancers did follow a usual pattern of growth, in your opinion would that assist the doctors in being able at least to control it to some extent? A. It would, I think.

Q. Now, coming to the subject of sterility, I think I told you that the complaint here charges that 25 to 50 milligrams methyl testosterone daily is dangerous because it may cause sterility. Now, in your experience, have you ever found testosterone to cause sterility, in an individual? [665]

A. No.

Q. What is the average age of an individual male coming to you for testosterone?

A. About 50.

Q. Have you found in those persons the subject of fertility or sterility to be an important factor as compared to relief from the symptoms of which they were complaining?

A. Not an important factor.

(Testimony of Dr. William A. Swim.)

Q. By the way, are vasectomies frequently done?

A. I don't know how frequently. I know of several that have been done.

Q. And a vasectomy is what?

A. Is a severing of the spermatic tube that leads from the testicle to the vas deferens.

Q. And a man who has had a vasectomy performed is unable to produce children?

A. That is right.

Q. And have you found that to be something that has been voluntarily applied for by the individual?

A. Yes.

Q. And for what purpose?

A. Well, as a contraceptive measure, to prevent having children. Once in a while, for less noble reasons.

Q. Now, one of the government witnesses, a doctor, Dr. Nelson, testified as follows, on page 99. He was testifying [666] or questions were being asked him about the effect of methyl testosterone upon sperm cell production and the production of testosterone by the interstitial cells and this question was asked him:

“Q. How could it, then, be determined whether or not there had been any damage to the testosterone-producing portions of the testes?

“A. The only way one can ascertain that is by examination of the testes and looking at the interstitial cells, noticing the atrophic changes that have been promoted by the inhibiting influences of the administered testosterone.

(Testimony of Dr. William A. Swim.)

“Q. Is that the microscopic examination of a slide a portion of the testes——

“A. Yes, sir——

“Q. Under a slide?

“A. Yes, sir.

“Q. (By the Court): Just how do you get at that? How do you examine the testes under a slide?

“A. A small piece of the testes is removed.

“Q. (By the Court): By surgical operation?

“A. By surgical operation, usually under a very simple local anesthetic. The tissue is properly fixed and sectioned and stained, the usual pathological procedure.

“Q. (By the Court): How would that be called for except by just some experiment? That does not seem like a practical [667] thing. Who would have that done?

“A. It is being done very, very widely, now.

“Q. It is?

“A. In cases of infertility or sterility or suspected disease or abnormal function of the testes. It is a widely recognized procedure at the present time.”

Now, Doctor, in the practice of medicine, other than in the experimental field, I will ask you, is such a procedure widely done?

A. No, I believe not.

Q. Do you know of any instances where it has been done? A. No, I do not.

Q. Now, Doctor, have you had occasion to read

(Testimony of Dr. William A. Swim.)

some of the literature on the subject of testosterone and its relationship to sterility?

A. Yes. I have read some.

Q. Now, as a result of that reading, what opinion do you have as to whether or not testosterone will affect a man's sterility?

A. In my opinion, it will not affect sterility.

Q. Now, in the literature that you have read, has the opinion been uniform or does it appear to be divided?

A. Divided.

Q. Two of the doctors that testified for the government, [668] Dr. Macdonald and Dr. Glass, stated unqualifiedly that estrogen is absolutely necessary to the growth of breast cancer. Now, I am going to ask you if, in your opinion—I am going to ask you if it is a fact that estrogen is absolutely necessary to the growth of breast cancer, or whether it is a matter of opinion, in your opinion.

A. In my opinion, it is quite a matter of opinion. In my opinion, it is not necessary.

Q. Will you state why?

A. Well, it is my own practice. I have seen cancers develop in the breast following what I thought was an absence of estrogen in the person.

Q. (By Mr. Elson): Now, Doctors Macdonald and Glass, and I am sure I am correct in interpreting the testimony, stated that the reason for their opinions in that connection was that the cancer following the administration of estrogens did not follow the usual pattern. Do you consider that to be a valid reason for their opinions that estrogen

(Testimony of Dr. William A. Swim.)

is absolutely necessary to the growth of breast cancer? A. No. There is no usual pattern.

Mr. Danielson: What is the page on that, Mr. Elson?

Mr. Elson: I don't know but, if you want to wait a minute, I can find it.

Mr. Danielson: If you can find that conveniently, I wish you would.

Mr. Elson: I can't find it conveniently but I can find it. It is on page 131. He stated he had, through diagnosis, treated such cases in which there was an affectation of this cancer or carcinoma; that these were young women with existing proved cancer of the breast, in which the duration of the cancer and its approximate rate of growth could be determined within reasonable limits; that, after the administration of the female sex hormone, and within a short time thereafter, there occurred in each of these instances to which he referred, a very rapid and alarming increase in the growth pattern of this breast cancer.

Mr. Danielson: That is referring to the administered [670] hormone as opposed to the other estrogen, isn't it?

Mr. Elson: I am talking about the natural. But I don't want to misinterpret the record.

Q. I will ask the witness do you believe, without the administration of estrogen—strike that. Do you believe that the natural estrogen in a woman's body is absolutely necessary to the growth of a breast cancer? A. No, sir.

(Testimony of Dr. William A. Swim.)

Q. Would it be for the same reasons you have stated? A. Yes.

Q. Doctors Macdonald and Glass stated that, in their opinion, estrogen administered caused breast cancer to accelerate in growth because the cancer did not follow a usual pattern. Now, do you believe that is a valid reason for their statement that estrogen is absolutely necessary for the growth of a breast cancer? A. I do not.

Q. Doctor, one of the products involved here is a half milligram of alpha estradiol, three tablets a day, which would be $1\frac{1}{2}$ milligrams per day. In your opinion, would that be a dangerous dosage insofar as causing the acceleration of an incipient cancer of the breast, cervix or uterus?

A. It would not.

Q. By the way, in your opinion, is it possible to diagnose or discover an incipient cancer of the breast, [671] cervix or uterus? A. No.

Q. Another product involved here is alpha estradiol in the quantity of .1 milligrams, to be taken three tablets per day for 10 days and thereafter one per day. In your opinion, would that amount be dangerous to the individual taking it?

A. No.

Q. Assuming that after taking that product uterine bleeding resulted, would you consider that uterine bleeding, if it had resulted from that, was dangerous to the woman? A. No.

Q. Why not?

A. Well, it is like normal menstrual bleeding,

(Testimony of Dr. William A. Swim.)

occasioned by the same process. It will stop when the drug is stopped. So it couldn't possibly affect her.

Q. And, if a woman started to bleed and came to you, what would you do?

A. If she had not been taking hormones—if she had been, I mean—I would stop the hormones.

Q. Then, what would you do following that?

A. If she stopped bleeding, I wouldn't do anything. If she needed hormones, I would give a smaller dose.

Q. Do you believe, then, that uterine bleeding, that caused by alpha estradiol, is of any danger to the patient herself? [672]

A. No danger.

Q. Are you familiar with these dosules that are used for breast development?

A. I am not familiar with them.

Q. Have you used them at all?

A. No; I have not.

Q. Dr. Heckel stated, on page 173, that, if testosterone were administered to a normal person, it would destroy the semeniferous tubules. Do you agree with Dr. Heckel in that statement?

A. I do not.

Q. Why don't you?

A. I have administered testosterone to people who have not borne children for years and had children born thereafter. So there must have been semeniferous tubules left.

Q. In other words, semeniferous tubules are

(Testimony of Dr. William A. Swim.)

absolutely necessary in order that a woman may produce? A. That is right.

Q. Doctor, let me ask you, in your opinion, would .1 milligrams of alpha estradiol, taken three times a day for a period of 10 days and thereafter one per day, have any effect in relieving a woman of the symptoms of the menopause?

A. Yes; it would.

Mr. Elson: You may cross-examine. [673]

Cross-Examination

By Mr. Danielson:

Q. Doctor, you say you are practicing internal medicine? A. Yes.

Q. Which is non-surgical, is that correct?

A. That is right.

Q. Do you perform any surgery, Doctor?

A. No.

Q. Then I take it you haven't removed any prostates?

A. Not since I was an intern.

Q. That would be not since 1918, is that right?

A. That is right.

The Court: Where is your place of practice?

The Witness: The Pacific Mutual Building, 523 West Sixth Street.

The Court: It is right downtown?

The Witness: Yes.

The Court: And what is the general nature of your clientele, of your patients?

(Testimony of Dr. William A. Swim.)

The Witness: I have a private practice of about 70 per cent; industrial accident work with various and sundry insurance companies of about 15 per cent; examination for unemployment insurance for the State of about 5 per cent, and examination and reports on injury cases of about 5 per cent. [674]

Q. Doctor, do I understand you to say that in your more or less 31 years of private practice here in Los Angeles you have discovered only three cases of cancer of the prostate? A. That is right.

Q. How long ago were they?

A. Well, one of them was shortly after I went into practice; one of them was about 10 years ago and one three years ago.

Q. You do not practice as an urologist, do you, Doctor? A. I do not.

Q. Nor specialize as an endocrinologist or gynecologist?

A. No. There is a difference, however, if I may explain that difference.

Q. You may, Doctor.

A. Endocrinology is a definite part of internal medicine, whereas urology is not any part of it.

Q. You do not specialize in the endocrinology phase of internal medicine?

A. No. I do general internal medicine only.

Q. And I believe you do no gynecology, is that correct?

A. I do medical gynecology but not surgical gynecology.

Q. Since you do no work as an urologist, I gather

(Testimony of Dr. William A. Swim.)

it is correct that no doctors would refer patients with [675] prostatitis or any other prostatic disturbance to you for treatment, would they?

A. I have had cases referred to me for treatment for prostatitis. And I must correct that one classification. I suppose there is such a thing as medical urology. We don't think of it quite in that term but there is such a thing. And prostatitis is an infection that can come in either field, either in the field of surgery or in the field of medicine, but it doesn't really involve in most cases the use of surgical instruments.

Q. No one refers surgical prostate cases to you, is that correct?

A. That is correct.

Q. And these three cancer cases to which you have referred would be the sum total of your professional experience in cancer of the prostate, is that correct?

A. Yes; that is correct.

Q. Then, Doctor, actually you have conducted no clinical or laboratory research into the effect of hormones on cancer of the prostate, have you?

A. That is right; I have not.

Q. And one of these cases took place shortly after you started practicing?

A. Yes.

Q. In other words, there would be not more than two in [676] the last 10 years?

A. That is right.

Q. Two during the period of testosterone, in other words?

A. That is right.

Q. And your opinion as to whether or not testosterone would accelerate the growth of a carcin-

(Testimony of Dr. William A. Swim.)

oma of the prostate would have to be confined to your observations of these two cases at the most, then, is that not correct?

A. Yes; it would be, personally.

Q. You did mention that in the case of a physical examination of a person coming in—do you know what I mean when I refer to the middle-aged symptoms? A. Yes.

Q. A patient coming in with these middle-aged symptoms, to which you are referring. You mentioned that in your practice you take a history, is that not correct? A. That is right.

Q. Did you perform a physical examination, enumerating the various parts of the body generally, including the reflexes and the appearance of the skin and examination of the prostate?

A. And the rectum; yes.

Q. You, likewise, testified, Doctor, that, if there was no indication of a malignancy, you would not go into the [677] more detailed examination such as biopsy and so forth? A. That is right.

Q. Doctor, in case there was some suspicion of malignancy, would you treat that yourself or would you refer the person to an urologist?

A. I would refer the patient to an urologist.

Q. In which event the urologist would conduct such additional examination as would be necessary to make a definite diagnosis, is that not correct?

A. That is right.

Q. And, if that required a biopsy, the biopsy would be performed, is that not correct?

(Testimony of Dr. William A. Swim.)

A. It might be. I don't know. I am not an urologist.

Q. That would be within the field of an urologist rather than the internal medical doctor?

A. Yes; it would be that field. But I am not sure whether it is still experimental or practical.

Q. When you testified as to this examination which you regularly conduct in your practice, you mentioned that, if there is no evidence of a constitutional disease, you would then administer or inject testosterone. Now, what did you refer to by "constitutional disease," to make that a little more clear?

A. Heart disease, chest diseases, like tuberculosis, and cirrhosis of the liver, diseases of the gastro-intestinal [678] tract, such as ulcer or cancer, and pancreatitis. I could continue the rest of the day with it.

Q. I suppose that is a good cross-section?

A. Yes.

Q. Doctor, in those cases would the use of testosterone be contra-indicated?

A. Not contra-indicated but would not be necessarily indicated.

Q. I see. Those conditions can, likewise, produce some of these symptoms we are referring to as the middle-aged symptoms, is that right?

A. Yes; they might contribute definitely to the production of those symptoms because they would help to lower the vitality of the interstitial cells of the testicle.

Q. And, likewise, these symptoms are not neces-

(Testimony of Dr. William A. Swim.)

sarily the exclusive indicia of the male climacteric, are they?

A. I believe that generally on the whole they are. I don't believe that they are a hundred per cent any of the other illnesses that I have mentioned.

Q. Yet you have testified that these other illnesses can produce these symptoms, isn't that correct?

A. They may produce some of the symptoms but not that complete symptom complex you have outlined there as the middle-aged disease.

Q. In your reference to this male climacteric or male [679] menopause, I believe you stated that you felt that there is a deficiency in male hormones in most men past the age of 50, or words to that effect?

A. Yes; I believe there is.

Q. And, likewise, when you have one of these cases which you say appears to indicate the use of testosterone, you give the patient a certain dosage and let him take it for a reasonable length of time and then, on the basis of trial and error, if that does not work, you quit it and give him something else, is that correct?

A. That is right.

Q. Now, let's take that one step farther. What would be one of these other things you would give him?

A. Well, I might give him bromides.

Q. And then suppose the bromides didn't work. Would you quit that and give him something else?

A. I might give him psychotherapy.

(Testimony of Dr. William A. Swim.)

Q. Suppose even that psychotherapy was lacking. What then?

A. We have patients that, no matter how many things we try, we have to keep on trying as long as the patient stays with us. No matter how long we try or what we try, we don't seem to be able to overcome certain symptoms that they complain of, which we designate as nervous symptoms.

Q. You mentioned about psychotherapy. Do you find, [680] Doctor, that sometimes the symptoms, no matter what kind of a pill you give a person, it might have a beneficial effect, just on a psychological basis.

A. Well, there may be a few patients who will react that way. I have never found that. I mean that would respond to pill therapy alone, because we have methods of detecting whether they respond to the real thing or spurious therapy.

Q. Doctor, you mentioned about the hormones being in short supply in many men past the age of 50. Just how do you determine that there is a deficiency in the male hormones.

A. By the clinical symptoms.

Q. Have you ever conducted any tests to determine whether a man's body is producing his requirements along that line?

A. No; I haven't.

Q. Have you ever conducted any research on this either in a laboratory or clinically?

A. No; I haven't.

Q. Would that statement apply to all of this

(Testimony of Dr. William A. Swim.)

hormone field, that is, not conducting research, that is, the female as well as the male?

A. I will say yes, it applies. Research, of course, is a broad subject. I will have to correct myself in saying that, when we try one thing and then another, that is research. [681]

Q. I suppose that everything one does is in a way research.

A. Yes. I wanted to make that clear; that is all.

Q. I am referring only to what you might call planned or formal research.

A. I have not done that. I am not in research practice.

Q. Doctor, you are aware, of course, are you not, that it is possible by laboratory means to determine whether a person produces testosterone?

A. It is possible to determine by laboratory means whether a person produces testosterone at the particular time the test is taken, yes, at the particular moment the test is taken. That is quite possible.

Q. And is it not also true, Doctor, that if it were essential to determine whether or not a person were deficient in hormones or was without hormones, as the case may be, if it were necessary to make a definite determination, you would have to perform some such laboratory experiment or analysis?

A. If it were necessary. But I do not believe that it is necessary and I don't believe that it gives us any information after it is performed.

Q. But, to get back to the question, Doctor, if it were [682] necessary to determine whether or not

(Testimony of Dr. William A. Swim.)

a person's gonads were producing the testosterone, then it would also be necessary to conduct such laboratory analysis, would it not?

* * *

Q. (By Mr. Danielson): I will repeat it. If it were necessary to determine, Doctor, definitely whether or not a person's body was producing testosterone, that determination would have to be made through laboratory analysis? A. Yes.

Q. It is, likewise, true, is it not, Doctor,—strike that. Do you know of any laboratory analysis that will determine that fact other than the testicular biopsy? A. No; I don't.

Q. Doctor, as to carcinoma of the breast in a female, have you ever seen carcinoma in the breast of a hypogonad woman? A. Yes.

Q. In one who does not have her natural supply or who has not had her natural supply of estrogen?

A. Oh, no; I never have, as I remember.

Q. You may have seen it in a castrate woman?

A. I don't remember having seen one in one who has [683] never had estrogen.

* * *

Q. Have you ever seen a cancer in the breast of a woman who has not had some supply, natural or artificial, of estrogen over a fairly long period of time in her life? A. Yes; I have.

Q. How long a period of time?

A. Ten years.

Q. Ten years would be the shortest period of time which you can presently recall?

(Testimony of Dr. William A. Swim.)

A. Yes; that I can recall.

Q. This is at pages 141 and 142. Referring, now, to certain testimony by Dr. Macdonald—do you know Dr. Macdonald here locally?

A. I think I have met him.

Q. Referring to certain testimony by Dr. Ian Macdonald, appearing at page 142 of this transcript, a portion of which testimony was referred to you by Mr. Elson, there is a statement that there must be a certain amount of circulating estrogen, [684] over a long period of years, in a woman's life, within herself, in order that breast cancer may develop. You have mentioned a period of ten years. On that basis, you would not disagree with Dr. Macdonald, is that not correct?

Mr. Elson: On what basis?

Q. (By Mr. Danielson): Do you disagree with Dr. Macdonald in his statement that there must be a certain amount of circulating estrogen, over a long period of years, in a woman's life, within herself, in order that breast cancer may develop?

A. I would not agree with that statement.

Q. Yet the shortest period of years in which the estrogen has been present and in which you have seen such cancer was ten years, is that not correct?

A. That is right, sir, if I understand your question.

Q. Will you explain that?

A. Yes. I understood the ten years applied to when the party was devoid of estrogenic material, before she developed a malignancy of the breast.

(Testimony of Dr. William A. Swim.)

That was my understanding of your earlier question.

Q. And that was the correct meaning of your answer then? A. Yes.

Q. Was this ten years past the menopause?

A. Yes; that is right. [685]

Q. In other words, this woman had gone through a menopause? A. Yes.

Q. And prior to that she had had her normal supply of estrogen, is that not correct?

A. Yes, sir.

Q. Which probably had endured for 10 years?

A. Yes; more than 10 years.

Q. Which would be, in effect, stating that you have never seen cancer of the breast in a woman who did not have her natural supply of estrogen for at least a long period of years?

A. I think that is correct; yes.

Q. Doctor, are you at all familiar with Dr. Charles Huggins, of Chicago, his writings?

A. I know who he is. The first time I really knew anything about Dr. Huggins was in connection with his researches for cancer.

Q. That is, the blood test? A. Yes.

Q. You are not particularly familiar with his work, then? A. No; I am not.

Q. Doctor, are you familiar personally or by reputation with Dr. Elmer Belt here in Los Angeles?

A. Both.

Q. Do you consider him to be an authority in his field?

(Testimony of Dr. William A. Swim.)

A. Well, I never accept any medical man as an authority anywhere.

Q. Do you consider him to be an eminent physician in his field, Doctor? A. Yes.

Q. Did I understand you to say you are not certain whether you know Dr. Macdonald either personally or otherwise?

A. I am not sure that I do.

Q. How about Dr. Samuel Glass in Beverly Hills?

A. No; I don't know Dr. Glass.

Q. Doctor, would you prescribe estrogen to a woman suffering from a cancer of the uterus or cervix? A. If she needed it.

Q. A pre-menstrual woman, before the menopause.

A. I might do that if I felt that she had symptoms that required it.

Q. Regardless of the cancer, is that correct?

A. Of course, "menopause" there must be defined.

Q. Probably I am inadequately experienced to define it to that point. I mean at the time when she is still producing her own supply of estrogen. [687]

A. Well, if she is producing her own supply of estrogen, I, naturally, would not prescribe it. But it wouldn't hurt her.

Q. But you wouldn't prescribe it. A. No.

Q. Would you prescribe testosterone for a man with cancer of the prostate?

A. If he needed it.

(Testimony of Dr. William A. Swim.)

Q. How would you determine whether he needed it, Doctor?

A. If he had the middle-aged symptoms.

Q. You would do that strictly on the basis of the symptomatology, is that correct? A. Yes.

Q. Without any research to determine whether he was producing testosterone?

A. Yes; that is correct.

Mr. Danielson: Thank you very much. That is all.

Mr. Elson: That is all.

* * *

Mr. Elson: We will call Mr. Parkinson.

ALLEN H. PARKINSON

a witness for the defendants, being first duly sworn,
testified as follows:

The Clerk: Which case is this?

* * *

Direct Examination

By Mr. Elson:

Q. Mr. Parkinson, you are the defendant in case No. 20,642? A. Yes, sir.

Q. You are the Allen H. Parkinson doing business as the Hudson Products Company?

A. Yes, sir.

Q. In count 1, it is alleged that you shipped certain tablets of testosterone, methyl testosterone, 10 milligrams, to a Robert Downing in Altoona,

(Testimony of Allen H. Parkinson.)

Pennsylvania, and accompanying that was a small circular, "The Male Hormone."

Mr. Neukom: Maybe your Honor can follow this better if we have this stipulation before the court——

* * *

The Court: For the purposes at hand, I have made what I believe is a sufficient examination of the stipulation. You may proceed. [695]

* * *

Q. Mr. Parkinson, will you take the stand again?
On June 24, 1949, did you go to Dr. Belt's office on Wilshire Boulevard? A. Yes, sir.

Q. Did you see anyone there? A. Yes, sir.

Q. About what time did you go there?

A. 10:00 a.m.

Q. Will you state whom you saw, what you did, and what conversations you had?

A. Yes, sir. At 10:00 a.m. on June 24th, I walked into Dr. Belt's office on Wilshire Boulevard, asked the receptionist if I could see one of the doctors. She referred me to a Dr. Ebert. Dr. Ebert asked me what I was there for [696] and I told him I would like some testosterone. He says, "Have you ever taken it before?" I says, "Yes; two years ago in Salt Lake City;" that a Dr. Openshaw prescribed some.

* * *

Q. (By Mr. Elson): Now, go ahead. What was the last statement made?

A. I walked into Dr. Ebert's office and I mentioned I would like some testosterone. He asked me

(Testimony of Allen H. Parkinson.)

if I had ever taken testosterone before. I said, "Yes; in Salt Lake City about two years ago," that Dr. Openshaw had given me some.

I mentioned I had had trouble with diminishing of the testicles and penis. And he said, "Are you taking it right now?" and I said "No," but that I continued taking it at frequent intervals because it has a tonic effect and makes me feel better. He said, "Would a 50 milligram shot of testosterone propionate be satisfactory?" And I said "Yes." I was then ushered into another room. In a few seconds, a laboratory assistant came in and took a blood sample. Then he went out of the room and Dr. Belt came in and gave me a brief rectal examination and went out of the room. Then another laboratory technician came in and injected me with a 50-milligram shot of testosterone propionate. [699]

The Court: How did you know?

The Witness: Dr. Ebert said it would be a 50-milligram shot of testosterone propionate. He left the room and then Dr. Belt put his head in the door and said, "What do you want on your prescription? How many tablets would you like on your prescription?" I mentioned that I would like 100 10-milligram tablets, or linguets—pardon me—of methyl testosterone. He said all right and then he had me urinate in three glasses. Then he asked me, "How do you take these, Allen?" I said, "I take three or four a day and then maybe I lay off three or four days, depending how I feel, and then I resume."

(Testimony of Allen H. Parkinson.)

He said all right. "What did the Doctor in Salt Lake City charge you?" And I said, "\$5.00." And he said, "All right. Pay the girl \$5.00 on your way out."

Q. (By Mr. Elson): Did he write out what purported to be a prescription at that time?

A. Yes, sir.

Q. I show you here what purports to be a prescription, on the prescription pad of Elmer Belt, Urologic Group. Is that the prescription that was written out? A. Yes, sir.

Q. Was that done in your presence?

A. No. He stepped out of the room to write it out but he handed it back to me. [700]

Q. Did you pay the girl \$5.00?

A. Yes, sir.

Q. And did you get a receipt for it?

A. Yes, sir.

Q. Is this the receipt that you received?

A. Yes, sir.

Mr. Elson: I offer in evidence the prescription referred to by the witness.

The Clerk: Defendants' Exhibit F in evidence.

Mr. Elson: And I offer as the next exhibit in order the paper referred to by the witness as a receipt.

The Clerk: Defendants' Exhibit G in evidence.

Q. (By Mr. Elson): Mr. Parkinson, did you, on June 30, 1949, call at the offices of a Dr. E. A. Gummig in Pasadena? A. Yes, sir.

Q. About what time of the day?

(Testimony of Allen H. Parkinson.)

* * *

Mr. Danielson: We will object, your Honor, to any testimony as to statements of, or acts by these doctors who have never been before this court. [703]

* * *

The Court: Well, this witness is a defendant in the case and naturally he is looking for every bit of evidence that he may consider in his defense. I think I should hear it.

Q. (By Mr. Elson): Now, Mr. Parkinson, did you call at the office of Dr. E. A. Gummig in Pasadena on June 30, 1949? A. Yes, sir.

Q. At 416 First Trust Building?

A. Yes, sir.

The Court: What is that name?

Mr. Elson: E. A. Gummig.

The Court: In Pasadena. When?

Mr. Elson: June 30th.

The Court: Yes, go ahead.

Q. (By Mr. Elson): Will you state what happened when you called at that office, without, however, telling us anything that the doctor told you?

* * *

Mr. Neukom: All right. We will withdraw our objection.

The Court: I will hear this, to this extent: The witness may testify that from these several, various doctors, naming them, he obtained a prescription or got an administration of testosterone, without a physical examination, or if there was a physical examination, he may describe that.

(Testimony of Allen H. Parkinson.)

Mr. Elson: All right.

Q. You called on a doctor at that address?

A. Yes, sir.

Q. Did you receive a prescription for Metandren Linguets?

A. Yes, sir, 100 tablets of methyl testosterone linguets.

Q. I show you a prescription on the prescription pad of E. A. Gummig, and ask you if that is the prescription that you received.

A. Yes, sir, it is.

Q. At any time during your visit at the doctor's office, did he lay his hands on you?

A. No, sir.

Mr. Elson: I offer this as Defendants' Exhibit next in [709] order.

The Clerk: Defendants' Exhibit H in evidence.)

(The document referred to was marked Defendants' Exhibit H and received in evidence.)

Mr. Neukom: Our objection is as I previously stated.

The Court: The objection will be noted in the record.

Q. (By Mr. Elson): By the way, what was the approximate total length of time that you were in Dr. Belt's office?

A. Not over 10 minutes.

Q. What was the approximate length of time that you were in Dr. Gummig's office?

A. Not over one minute?

Mr. Elson: Cross-examine.

(Testimony of Allen H. Parkinson.)

Cross-Examination

By Mr. Danielson:

Q. Now, who was the first doctor you saw in Dr. Belt's offices, Mr. Parkinson? A. Dr. Ebiert.

Q. And precisely, what did you say to him?

A. I told him I would like some testosterone.

Q. Did you tell him you needed any testosterone?

A. I told him I would like some.

Q. What else did you tell him?

A. And he asked me if I had taken testosterone before. I said, "Yes, sir, approximately two years ago, a Dr. Openshaw in Salt Lake City administered some testosterone to me for receding of the testicles and penis," and it helped that condition and I continued taking it off and on because of the tonic effect.

Then he asked me if I had any children. I told him two. And if I was married, my age and my address. And I told him I would like a shot and he said a 50 milligram shot of testosterone propionate, and then I was ushered in this other room.

Q. And wasn't it true that Dr. Openshaw had so treated you? A. No, it was not.

Q. You were lying at that time, were you not, Mr. Parkinson? A. Yes, sir.

Q. You sell testosterone, do you not, Mr. Parkinson? A. Yes, sir.

Q. You have been selling it for some time, have you not? A. Yes, sir.

Q. You actually did not need any testosterone, did you?

(Testimony of Allen H. Parkinson.)

A. No. The shot did me no good whatsoever one way or the other.

Q. At least that is your opinion?

A. That is my opinion.

Q. You are not a doctor, are you?

A. No, sir.

Q. Are you a pharmacist? A. No, sir.

Q. You really don't know what happened to you as a result of the testosterone propionate, do you?

A. All I know, it had no effects on me whatsoever.

Q. All you know is you don't know what happened to you whatsoever?

A. No. I had no ill effects.

Q. Precisely, what samples were taken from you at Dr. Belt's office?

A. A blood sample and three urine tests.

Q. A blood sample was taken and three urine samples, is that correct? A. Yes.

Q. What was your purpose in going to Dr. Belt's office.

A. After hearing his testimony in this courtroom, it was unbelievable to me that those tests had been made, that although I am not a pharmacist, I have consulted with other doctors on the efficaciousness or harmful effects of testosterone, including Dr. Glass, and I know that those tests, from the doctors I consulted with, are not made, and the general consensus of opinion is that testosterone is not [712] dangerous and I could not believe my ears when I

(Testimony of Allen H. Parkinson.)

heard Dr. Belt said that, and I wanted to prove it to my own satisfaction.

Q. Do you know what tests Dr. Belt made?

A. I do know this, I was only there 10 minutes and that an elaborate test could not be made on my blood and urine in that time. That is my personal opinion.

Q. But you did tell him you had been to see Dr. Openshaw before?

A. I told Dr. Ebiert that it was approximately two years before that and that the condition was corrected and that now I was taking it for a tonic effect, and also Dr. Belt examined my testicles and penis and said, "They look all right now," and I said, "They are."

Q. He said they looked all right.

A. Yes, sir.

Q. Are you sure that he did not say they were atrophied or too small?

A. No, sir. He said they looked all right. Those are his exact words.

Q. But you did tell him, anyway, that Dr. Openshaw had prescribed this testosterone to you before?

A. I told Dr. Ebiert that was two years before.

Q. Did you tell that to Dr. Belt?

A. No. Dr. Belt did not ask me.

Q. Then, Dr. Ebiert left the room, before you got the [713] shot of testosterone?

A. Yes, sir.

Q. And before you got the prescription?

A. Yes, sir.

(Testimony of Allen H. Parkinson.)

Q. You do not know whether he consulted with Dr. Belt or not, then, do you?

A. I have no idea.

Q. You did testify that Dr. Belt conducted a rectal examination, did you not? A. Yes, sir.

Q. He felt your prostate apparently, then?

A. Yes, sir.

Q. Again, what was your purpose in going to Dr. Belt's office? Was it not to see if you could trick him? A. No, sir.

Q. Did you want testosterone when you went in there, actually want it?

A. No, I went there to find out on the fact testified to, if it was true what he said.

Q. You weren't going in there in good faith for medical treatment, were you?

A. I was going there in good faith to see if Dr. Belt's office would do what he claimed.

Q. Were you going in good faith for medical treatment? A. No, sir. [714]

Q. Did you in good faith tell him your past medical history?

A. I was not asked for my past medical history.

Q. Did you tell him in good faith you had been to see Dr. Openshaw? A. No.

Q. In other words, you lied to him, then. Your purpose in going there was not for medical treatment, was it?

A. My purpose in going there was for information.

Q. Just answer my question. A. No, sir.

(Testimony of Allen H. Parkinson.)

Q. And you think that the total time that you remained within Dr. Belt's office was not over 10 minutes? A. Yes, sir.

Q. Now, you went to Dr. Gummig in Pasadena, and you already had a prescription for a hundred tablets of methyl testosterone, didn't you.

A. Yes, sir.

Q. And you went for another prescription for a hundred tablets at his office, did you not?

A. Yes, sir.

Q. Did you go in there in good faith, Mr. Parkinson?

A. I was going in there in good faith, in this respect, I was going in there in good faith to find out if a general practitioner did make an examination, if he did feel that it [715] was necessary.

Q. Were you going there for medical treatment that you needed? A. No.

Q. Or that you even thought you needed?

A. No.

Q. You were going there, were you not, only to try to procure more evidence, is that correct?

A. I was going there to find out what the general practitioner thought.

Q. Just answer my question. Were you going there to try to procure some more evidence for the purpose of this specific testimony. A. Yes, sir.

Q. And that was the only reason you went to see Dr. Belt, was it not? A. Yes, sir.

Q. You were trying to manufacture evidence, was that not correct? Just answer the question.

(Testimony of Allen H. Parkinson.)

A. Yes, sir.

Q. How old are you, Mr. Parkinson?

A. Thirty years old.

Q. When were you born?

A. January 26, 1919.

Q. You are married, are you? [716]

A. Yes, sir.

Q. Did you mention anything of that sort to Dr. Ebiert?

A. Dr. Ebiert asked me first——

Q. What address did you give Dr. Ebiert?

A. 341 Harding Street—G Street, pardon me, Salt Lake City, Utah, which was my address at that time two years ago.

Q. But it is not your address today?

A. No, sir.

* * *

Q. (By Mr. Danielson): Your address as of June 24, 1949, was what?

A. 341 Harding Street, Long Beach, California.

Q. And what address did you give to Dr. Belt?

A. 341 G Street, Salt Lake City, Utah.

Q. Was that your correct address?

A. No, sir.

Q. As a matter of fact, you were giving him a false address, were you not? A. Yes, sir. [717]

Q. And why did you give him a false address?

A. For the simple reason that I would be asked why I did not go to my local physician, which would——

(Testimony of Allen H. Parkinson.)

Q. Certainly embarrass you, would it not, Mr. Parkinson?

A. Yes, sir—not quite embarrass me, but I wouldn't have what I went there for.

Q. You did not need any prescription for testosterone, did you? A. No.

Q. You sell it? A. Yes, sir.

Q. You buy it wholesale, you can buy it wholesale? A. I manufacture it.

Q. You even manufacture it? A. Yes, sir.

Q. As well as evidence, is that correct?

A. I beg your pardon? [718]

* * *

Q. You, then, cannot only buy it wholesale, you can get it lower than wholesale, you make it?

A. Yes, sir.

Q. And you could have bought it from Mr. Clemens without a prescription, couldn't you.

A. I could buy it at quite a few drugstores or go to a doctor and ask for a prescription.

Q. You could have bought it from Mr. Clemens, without a prescription? A. Yes, sir.

Q. As well as from yourself? A. Yes, sir.

Q. The entire purpose of this entire journey, little foray of yours, was merely in bad faith to get prescriptions from doctors?

* * *

A. To determine the truth.

Q. To in bad faith, get prescriptions from doctors for testosterone, isn't that a fact?

(Testimony of Allen H. Parkinson.)

A. I was not in bad faith.

Q. Did you need the prescriptions?

A. No, sir. [719]

Q. But you went to them?

A. But I needed it to find out the truth.

Q. Now, did you tell Dr. Belt or any representative of his office that you had been taking testosterone over a period of about two years?

A. As I said before, approximately two years ago, that Dr. Openshaw had administered some testosterone to me and that off and on I had taken it, which is true, because it made me feel better.

Q. Now, did you tell them that Dr. Openshaw had been treating you with about 50 milligrams a week of testosterone? A. No, sir.

Q. Or what dosage?

A. No, sir. That suggestion came from Dr. Ebiert.

Q. What dosage did you tell them that you received? A. He did not ask me.

Q. What type of testosterone did you tell him you had been receiving?

A. He did not ask me that. He said, "Would you like a 50 milligram shot of testosterone propionate?"

* * *

Q. (By Mr. Danielson): What type of testosterone did you tell him you had been taking? [720]

A. I did not tell him. I said I had been taking testosterone, that was all.

Q. Didn't you tell him you had been taking testosterone propionate or Neo-Hombreol?

(Testimony of Allen H. Parkinson.)

A. No, sir.

Q. Did you tell him you had been taking testosterone intra-muscularly? A. No, sir.

Q. Did you tell him you had been taking testosterone, these 10 milligram tablets or linquets to which you referred? A. No, sir.

Q. Did you tell him you had been taking them three times a day? A. I told Dr. Ebiert that.

Q. That you had been taking them three times a day?

A. No, sir. Three or four times a day.

Q. Three or four times a day. Did you tell Dr. Belt who referred you to his office.

A. No. I was not asked that.

Q. Did you not tell Dr. Belt or his representative that Dr. Openshaw had recommended that you visit his office in Los Angeles?

A. No. I did not say that.

Q. You did not say that?

A. I said Dr. Openshaw had treated me two years ago. [721]

Q. Just specifically, did you tell Dr. Belt or his representative that Dr. Openshaw had recommended that you visit his office during your stay in Los Angeles, for testosterone propionate or any other testosterone? A. No, sir.

Q. Or to renew his prescription?

A. No, sir.

Q. Did you tell him that you were staying in Los Angeles very long? A. No, sir.

(Testimony of Allen H. Parkinson.)

Q. Where did you tell him you were going?

A. I told him I was passing through.

Q. Where did you say you were going?

A. On my way to San Francisco.

Q. Did you tell him that your testicles had begun to atrophy two years ago?

A. I told Dr. Ebiert, not Dr. Belt.

Q. You told one of them that your testicles had begun to atrophy two years ago?

A. I told them that they had been receding.

Q. Was that true? A. No, sir.

Q. That was a lie, too, is that correct?

A. Yes.

Q. And you told that lie to a doctor in what, in so [722] far as he was concerned, was an honest visit of a patient to a doctor for treatment, is that correct?

Mr. Elson: I object to that on the grounds it is improper cross-examination and it calls for a conclusion of the witness in so far as what the doctor might have thought.

Mr. Danielson: I believe that the question is proper.

The Court: I think it does call for a conclusion.

Mr. Danielson: Thank you. I will withdraw that.

Q. Did you tell the doctor that you were there without need—you were there only to procure some evidence for this trial? A. No, sir.

Q. Did you tell him that you were there for treatment?

(Testimony of Allen H. Parkinson.)

A. I told him I was there because I wanted some testosterone.

Q. You told him you needed some?

A. I told him I wanted some testosterone.

Q. You told him the reason you wanted it was for a tonic?

A. No. I told him I had used testosterone before.

Q. You told him you had taken it for a tonic effect?

A. Yes, sir. That is true.

Q. You did not tell him anything that would lead him to believe that you did not need it for tonic effect?

A. No, sir, nor did I tell him I was suffering from [723] any ailments. I was not asking for it for that purpose.

Q. Did you tell him that you were there for any reason other than the usual patient-physician relationship?

A. No. I told him I wanted some testosterone.

Q. And at that time you told him that your testicles had begun to shrink?

A. Two years ago, but they were all right now, and Dr. Belt looked at me and said they were all right.

Q. But, nevertheless, you did not tell the truth about that physical condition?

A. You are right, sir.

Q. Did not Dr. Belt or his associate tell you that they could not give you testosterone without conducting a physical examination.

A. I was not told that.

(Testimony of Allen H. Parkinson.)

Q. Did they not tell you that they could not give you the testosterone without conducting this examination to assure themselves that the material would do you no harm?

A. No. They did not tell me that.

Q. Such an examination was carried out, however, was it not? A. Yes, sir.

Q. Just what examination was carried out, what portions of your body were examined?

A. Rectal. [724]

Q. Any other? A. No, sir.

Q. Did they examine your eyes?

A. No, sir.

Q. Did they hold a light up before your eyes in a manner that doctors do in a general examination? A. No, sir.

Q. Did they examine your ears and nose?

A. No, sir.

Q. Examine your throat? A. No, sir.

Q. Did they examine your neck, feel of your thyroid? A. No, sir.

Q. Did they thump your chest? A. No, sir.

Q. Or back? Did they take your blood pressure?

A. No, sir.

Q. Did they take your pulse? A. No, sir.

Q. Did they listen to your heart, with this head phone set that doctors use? A. No.

Q. Did they feel of your abdomen?

A. No, sir.

Q. Did they test your reflexes, hit you with a hammer [725] on the knee? A. No, sir.

(Testimony of Allen H. Parkinson.)

Q. Did they examine your penis?

A. Yes, sir, and my testicles.

Q. They examined your testicles. Did he make an examination of your scrotum by feel?

A. Just a cursory examination, yes, sir.

Q. What examination?

A. Just a brief examination.

Q. As to whether it is cursory, let us leave that to experts, Mr Parkinson.

A. Yes, sir.

Q. He then felt of your—he did examine your prostate, in the rectal examination?

A. Yes, sir.

Q. Did he make any comment at that time?

A. He said it was all right. He said he could feel no hardness, to use his exact words.

Q. Then, apparently he was looking for hardness, then, is that correct?

A. Yes, sir.

Q. He did make urine tests?

A. Yes, sir.

The Witness: He took my urine, let us put it that way. [726]

Q. (By Mr. Danielson): That is correct, he took your urine. And he also took blood samples?

A. Yes, sir, blood sample.

Q. (By the Court): Did you note how many cubic centimeters he took of blood?

A. I would say about 50, sir, but at best that would be rough.

Q. (By Mr. Danielson): Have you done any laboratory work, Mr. Parkinson?

A. No, sir.

Q. Have you ever taken a blood sample?

A. No, sir.

(Testimony of Allen H. Parkinson.)

Q. You are not a chemist? A. No, sir.

Q. Nor a biologist? A. No, sir.

Q. What has been your business, Mr. Parkinson?

A. Previous to going into this business, I was general sales manager of the Piuma Wine Company. Previous to that I was national sales manager of Mercury Record Corporation.

Q. Is that phonograph records?

A. Yes, sir.

Q. How long have you been in this business, Mr. Parkinson?

A. Approximately two years. [727]

Q. As a matter of fact, you would not know what 50 cubic centimeters looks like, would you?

A. Yes, sir.

Q. How much is 50 cubic centimeters?

A. Well, it would come approximately to there (indicating on water glass).

Mr. Elson: There, indicating about an inch or three-quarters of an inch from the bottom——

A. Yes, sir.

Q. ——of a water-glass? A. Yes, sir.

The Court: How many cubic centimeters are there to the ounce?

A. I don't know, sir. The reason why I am familiar with that particular one is that I happen to have a viol in my office with centimeters on it.

Q. (By Mr. Danielson): Have you ever been known as Hazen A. Parkinson, Mr. Parkinson?

A. Yes, sir.

Q. Or just plain Allan Hazen Parkinson?

(Testimony of Allen H. Parkinson.)

A. Yes, sir.

Q. Or Allan Parkinson? A. Yes, sir.

Q. You have lived in Salt Lake City, I see, is that correct? [728] A. Yes, sir.

Q. And you have at least either lived in or been in Las Vegas, Nevada, is that not correct?

A. Yes, sir.

Q. Have you ever been convicted of a felony, Mr. Parkinson? A. No, sir.

Q. Now, Mr. Parkinson, I see you have been here from time to time. I also notice that you weren't here on a couple of days. Did you happen to be here, by any chance, during Dr. Belt's testimony on July 5th, on Tuesday of this week?

A. No, sir.

Q. You remained absent, when Dr. Belt was here, is that correct? A. Yes, sir.

Q. You did show up in the afternoon, I believe, did you not? A. Yes, sir.

Q. Now, Mr. Parkinson, Dr. Belt testified (this appears on page 436 of the transcript, starting at line 20):

"Now, you mentioned the precautionary examinations which were given." This was a question to Dr. Belt. "Assume for a moment, Doctor, that the patient told you that he was referred by another doctor who gave him such drugs from time to time, would that change the procedure at all? [729]

"A. Well, if a patient comes to me referred by another physician, I always allow the other physician the benefit of whatever doubt that might exist

(Testimony of Allen H. Parkinson.)

in my mind and my tendency is to go on with the original treatment he has established until I can communicate with him and discuss the problem with him. It is possible that the patient may not tell me things that he has communicated to his other physician. It is possible that I may not see things in that patient that the other physician saw. So, in the first place, a generously disposed human being would not say right away, 'Oh, your doctor is doing the wrong thing. My goodness, this is the trouble.' But you would conform to the treatment until you had an opportunity for discussion and coming to a common understanding of that."

Now, as a matter of fact, Mr. Parkinson, you told Dr. Belt that you had been referred by Dr. Openshaw, is that not correct?

A. No. I mentioned that two years ago I had been to Dr. Openshaw.

Q. And that you went back to him for the same purpose, to get some testosterone?

A. Yes, sir.

Q. Now did you give Dr. Belt Dr. Openshaw's address?

A. No, sir. At Salt Lake City, I gave Salt Lake City, but not the street address. [730]

Q. Did you give him Dr. Openshaw's name, I mean full name?

A. Yes, Dr. Openshaw.

Q. You told Dr. Belt that you were going to San Francisco and were here only temporarily.

A. I told Dr. Ebiert.

Q. Dr. Ebiert?

A. Yes, sir.

(Testimony of Allen H. Parkinson.)

Q. Who was in Dr. Belt's office, also, at that time? A. Yes, Dr. Belt's clinic.

Q. And who, so far as you know, could or at least had an opportunity to talk to Dr. Belt prior to the time that Dr. Belt saw you?

A. He could have.

Q. And how did you happen to go to Pasadena, Mr. Parkinson?

A. My brother lives in Altadena and I was driving through and stopped off at this place, and while I was there I stopped in Pasadena to pick up the prescription.

Q. Dr. Belt did not refer you to Dr. Gummig, did he?

A. No, sir, and I did not tell Dr. Gummig that he did.

Q. Did you tell Dr. Gummig that Dr. Openshaw had? A. No, sir.

Q. Dr. Belt said he would—in fact, he did give you a prescription which would carry you over for a time at least, [731] isn't that correct?

A. Quite a time.

Q. And your purpose in going to Dr. Gummig was identical with your purpose in going to Dr. Belt, is that correct? A. Yes, sir.

Q. And you say that this entire examination cost you but \$5 at Dr. Belt's office?

A. Yes, sir.

Q. And that included the general physical?

Mr. Elson: No, no.

A. No, no. There was no general physical.

(Testimony of Allen H. Parkinson.)

Q. (By Mr. Danielson): Well, yes, the general physical, when he examined your body from head to foot?

A. He did not examine my body from head to foot.

Mr. Elson: The examinations to which he has testified?

Q. (By Mr. Danielson): The examinations to which you have testified? A. Yes, sir.

Q. And likewise, the urine samples and whatever analysis may have followed from it?

A. Yes.

Q. Likewise the blood sample and whatever analysis may have followed from that?

A. Yes, sir.

Q. It was \$5, is that correct? [732]

A. Yes, sir.

Q. That was the total charge? A. Yes.

* * *

Q. (By Mr. Danielson): Mr. Parkinson, you say that you did not believe that Dr. Belt was telling the truth up here on the witness stand, is that correct?

A. I did not mean it quite that way. The truth, that is a rather broad statement. Put it this way, I did not think that he went through the procedure that he said on the stand.

Q. You don't feel that the procedures he has described here on the stand, then, would necessarily be carried out by him in practice, is that correct?

(Testimony of Allen H. Parkinson.)

A. Yes, sir.

Q. You heard the testimony I read to you from Dr. Belt's testimony to the effect that when a patient comes to his office, having been referred by some other doctor, he would go right along with the other doctor's previous treatment?

A. I did not state I had been referred by Dr. Openshaw. I stated I had been to Dr. Openshaw some two years before.

Q. (By Mr. Danielson): You have heard the testimony, that I have read to you, to the effect that Dr. Belt said that if a patient comes into his office on referral from another doctor, he would tend to go along with the first doctor's treatment until he had a chance to communicate with that doctor and reach an agreement with him?

A. Yes, sir.

Q. Would it surprise you to think that Dr. Belt may have made such a communication with Dr. Openshaw?

A. Well, I am neutral on it.

Q. Would you be surprised if he carried out that practice which he testified to?

A. I have no opinion on that.

Mr. Danielson: No further questions. [734]

Redirect Examination

By Mr. Elson:

Q. Just one question. On this day that you went up there, you had this examination at 10:00 o'clock in the morning, was it?

A. Yes, sir.

(Testimony of Allen H. Parkinson.)

Q. Did you return to the court room that morning, after this examination?

A. I was here at 11:00 o'clock.

Mr. Elson: That is all.

Recross-Examination

By Mr. Danielson:

Q. Mr. Parkinson, did you ever go back to Dr. Belt for the results of your examination?

A. I never asked him for them.

Q. Did he ever offer them to you?

A. No, sir.

Q. Just for the sake of the record, are you the same Allen H. Parkinson who is a defendant in the case of United States vs. Allen H. Parkinson?

A. Yes, sir.

Mr. Danielson: Thank you. That is all.

* * *

ALLEN H. PARKINSON

a witness for the defendants, being heretofore duly sworn, resumed the stand and testified further as follows:

Recross-Examination

By Mr. Danielson:

Q. Mr. Parkinson, you testified that you saw Dr. Openshaw two years ago, is that correct?

A. Yes, sir.

Q. Have you seen him since that time?

A. Yes, sir.

(Testimony of Allen H. Parkinson.)

Q. Is it not true you saw him about four months ago, more or less, in Salt Lake City? Is that correct? A. No, sir.

Q. When was the last time you did see Dr. Openshaw?

A. I was on my way back East and saw him a little while ago.

Q. Do you mean during the latter part of June, possibly? A. Yes, sir.

Q. During the time this trial has been in session?

A. Yes, sir.

Q. Did you not, likewise, see him several months ago? A. No, sir.

Q. Who was present with you in Dr. Openshaw's office [736] when you did see him a few weeks ago the last time you saw him? A. My father.

Q. Had your father, to your knowledge, received treatment from Dr. Openshaw before?

A. In what respect?

Q. In any professional respect.

A. I think so but I couldn't say definitely.

* * *

Q. By Mr. Danielson: Did you invite or ask or request Dr. Openshaw to come to Los Angeles and appear as a witness in this case? A. Yes, sir.

Q. Did you see Dr. Openshaw before or after you saw Dr. Belt on June 24th? A. After.

Q. After you saw Dr. Belt? A. Yes, sir.

Q. Did you tell Dr. Openshaw you had seen Dr. Belt? A. No, sir.

(Testimony of Allen H. Parkinson.)

Q. Or did you tell Dr. Belt you were going to see Dr. Openshaw? A. No, sir.

Q. What treatment did Dr. Openshaw give you?

A. No treatment.

Q. Did you request any treatment of him?

A. No, sir.

Q. Your purpose in going to see him was merely to invite him to be a witness here, is that correct?

A. Yes, sir.

* * *

Mr. Elson: Mrs. Shinglman, please.

HANNAH SHINGLMAN

called as a witness for the defendants, being first duly sworn, testified as follows:

The Clerk: Will you state your full name?

The Witness: Hannah Shinglman.

The Clerk: How do you spell it?

The Witness: H-a-n-n-a-h S-h-i-n-g-l-m-a-n;
9250 Olympic Boulevard, Beverly Hills.

Direct Examination

By Mr. Elson:

Q. Mrs. Shinglman, on June 27th of [739] this year, did you go to the office of the Elmer Belt Urologic Group in Beverly Hills?

A. Yes, sir.

Q. Will you state, please, what you did and whom you saw. In other words what took place?

Mr. Neukom: Now, your Honor, we are going to object to this. [740]

* * *

(Testimony of Hannah Shinglman.)

The Court: Overruled.

Q. (By Mr. Elson): You had gotten to the office of the Elmer Belt Urologic Group in Beverly Hills. Now, will you state what happened, Mrs. Shinglman?

A. Yes. I walked into the office and asked to see Dr. Belt and the nurse told me he was only there on Tuesday and Thursday mornings. I decided to leave but, on thought, I decided to go back in again and ask to see another doctor. So she told me to wait, that Dr. Letourneau was in and would speak to me. And she asked me of what nature I had come there and I told her I wished to discuss my husband with the doctor, personally. So I waited for Dr. Letourneau and he came into the office and he asked me what he could do for me and I told him we had been here around six or eight months and that previous to this time my husband had not been feeling well for the last few years; that he had been very nervous and was very jumpy and irritable, and we figured he must be going through the male change, and that a doctor in Chicago had given him some shots, and that he had done so well that he had put him on tablets. And I showed him the bottle, and he had run out, and so he gave me a prescription for those [745] tablets. He told me, if I liked, perhaps my husband would like to come in for examination. I told him he was quite busy. And in the meantime he wrote out the prescription.

(Testimony of Hannah Shinglman.)

Q. Was that done in your presence?

A. Yes, sir.

Q. I show you here a prescription on the prescription pad of the Elmer Belt Urologic Group, to Mrs. Shinglman, June 27, 1949, for 100 Metandren Linguets, 25 milligrams, one daily, and signed "M. Letourneau, M. D." Is that the prescription you received at that time? A. Yes, sir

Mr. Elson: I offer this in evidence as the defendants' next exhibit in order.

Mr. Danielson: The same objection.

Mr. Elson: And you may cross-examine.

The Clerk: That will be Defendants' Exhibit I in evidence.

Cross-Examination

By Mr. Danielson:

Q. Did you say your name is Mrs. Hannah Shinglman? A. That is correct.

Q. Are you married? A. Yes, sir.

Q. Do you still have a husband?

A. Yes, sir. [746]

Q. And you are living with him, is that correct?

A. Yes, sir.

Q. What is your business, Mrs. Shinglman?

A. I am a housewife.

Q. Do you have any other business?

A. No, sir.

Q. Are you being paid for testifying here today? A. I don't know.

(Testimony of Hannah Shinglman.)

Q. What agreement do you have as to being paid to testify here today?

A. No agreement.

Q. Who invited you to testify?

A. Mr. Elson.

Q. You were at Dr. Belt's office on June 27th?

A. Yes, sir.

Q. And at whose instigation did you go there?

A. Mr. Elson's.

Q. You hadn't planned to go there until Mr. Elson suggested you do so? A. Correct.

Q. Where do you live?

A. 9250 Olympic Boulevard, Beverly Hills.

Q. Where is his office?

A. On Lasky Drive.

Q. That is about how far from where you live?

A. Approximately a mile or a mile and a half.

Q. Did you tell Dr. Letourneau that you were there solely at the instigation of Mr. Elson?

A. No, sir.

Q. You said you were there because you wanted some tablets for your husband? A. Yes, sir.

Q. As a matter of fact, does your husband use such tablets? A. Yes, sir; he does.

Q. And has he been using them for some time?

A. Yes, sir.

Q. And you did show Dr. Letourneau the bottle, the old prescription?

A. Yes, sir. This is the bottle I gave him.

Q. And you told Dr. Letourneau that your husband had been taking these as the result of the

(Testimony of Hannah Shinglman.)

treatment of some doctor in Chicago, on his suggestion? A. Yes, sir.

Q. And it was after that that Dr. Letourneau gave you the prescription? A. Yes, sir.

Q. And no charge for the prescription?

A. No, sir.

Q. Just for the sake of the record, this label on this [748] bottle says, "100 tablets Metandren, Ciba's, trade name for methyl testosterone; each tablet contains 25 milligrams of methyl testosterone." That is correct, is it? A. Yes, sir.

Q. Were you subpoenaed to appear here, Mrs. Shinglman? A. No, sir.

Q. Have you received any pay at all?

A. No, sir.

Q. Any pay for appearing here?

A. No, sir.

Q. Has any promise or offer been made to you for payment? A. No, sir.

Q. Do you appear frequently as a witness in cases of this type? A. No, sir.

Q. Have you ever appeared as a witness professionally? A. No, sir.

Q. This is your first professional trip as a witness, then, is that correct?

A. It depends on what you call "professional."

Q. You have no other purpose in being here, have you? A. No, sir.

Q. You told Dr. Letourneau that you were here temporarily, isn't that correct? [749]

A. No. I told him we had only been here six or eight months.

(Testimony of Hannah Shinglman.)

Q. Who referred you to Dr. Letourneau?

A. Nobody.

Q. You just dropped in off the street, did you?

You had no reference? A. He didn't ask me.

Q. Did you tell him whether you had any reference? A. No, sir.

Q. I believe you testified, Mrs. Shinglman, that, after showing the doctor the bottle and telling him this background about the medicine having been used by your husband—you did testify, did you not, that you then asked him to please give you some more, that the bottle was running dry?

A. Yes, sir.

Q. And I believe you also said that the doctor suggested that you have your husband come in for examination, is that not correct?

A. If he liked.

Q. Of course, you couldn't force him to come in, is that correct? Isn't that correct?

A. I don't know.

Q. The doctor couldn't force him to come in for examination? That is correct, isn't it? [750]

A. I don't know. [751]

* * *

Mr. Elson: Mr. Parkinson.

HAZEN S. PARKINSON

called as a witness on behalf of the defendants, being first duly sworn, testified as follows:

The Clerk: Your full name?

A. Hazen S. Parkinson.

(Testimony of Hazen S. Parkinson.)

Direct Examination

By Mr. Elson:

Q. Mr. Parkinson, will you please speak loudly so that we call all hear you? A. Yes, sir.

Q. Mr. Parkinson, are you the father of Allen H. Parkinson? A. Yes, sir.

Q. Defendant in one of these actions?

A. Yes, sir.

Q. Did you recently accompany your son on a trip to Chicago? A. Yes, sir.

Q. By automobile? A. Yes, sir.

Q. And you arrived in Chicago on what day?

A. The 29th of June, I think it was—the 26th of June. [753]

Q. What day of the week would that be?

Q. What? A. Sunday.

Q. Sunday. On the following day, Monday, which was the 27th, of course, did you go to the office of Dr. Norris J. Heckel? A. Yes, sir.

Q. About what time of day?

A. It was shortly after 1:00 o'clock.

Q. In the afternoon? A. Yes, sir.

Q. Did you go into the office? A. Yes, sir.

Q. All right now, will you state who you saw and what happened?

A. I met the nurse and asked if I could see Dr. Heckel.

Q. Speak a little louder.

A. I met the nurse, first, and she asked me

(Testimony of Hazen S. Parkinson.)

what I wanted and I told her I would like to see Dr. Heckel, if he was in.

She said, "Be seated just a moment." And she went back and I suppose seen Dr. Heckel and she told me to be seated and he would see me shortly.

Mr. Neukom: Now, your Honor, I want to object. Here [754] is Dr. Heckel, a busy urologist back in Chicago. Now, we knew about this, and we have letters from Dr. Heckel explaining all this to us. This has not been a surprise to the Government. [755]

* * *

The Court: I don't want to hear any of the evidence of this witness' experience, nor do I want to see the letters of Dr. Heckel. He was on the stand here, called for a purpose. He testified as to that. Then he went into, upon examination, cross-examination or otherwise, as to what the average doctor might do, and I don't know that he is any more competent to testify as to that than a layman. I did not attach much, if any, importance or credence to his views as to what an average practitioner might do, in prescribing or administering this medicine. I don't want to go any further into that. [760]

* * *

The Court: I don't care for it. There isn't any doubt but what you could make a showing that thousands of doctors prescribe what a patient asks for. Unquestionably, you can find doctors who

(Testimony of Hazen S. Parkinson.)

will commit criminal abortion. Sometimes doctors don't stick to their own code. I don't care for any more of that evidence because I am satisfied, in my own mind, that this could go on ad infinitum. So I think it would be well to withdraw this witness.

Mr. Elson: Your Honor, for the purpose of the record, may I make an offer of proof in these two instances?

The Court: Yes; surely.

Mr. Elson: It will take me a little time to do it but, if you will bear with me, I would like to do it. With reference to this witness, Mr. H. S. Parkinson, I offer to prove that, on June 27, 1949, he went to the office of Dr. Norris J. Heckel shortly after 1:00 o'clock p.m.; that he saw the nurse first and she asked him who he wanted to see [762] there and he said some of the fellows in the garage in the hotel where he was staying sent him; that she first took his name and his address in Chicago, told him to be seated and she would see the doctor; that she went to see the doctor and then he waited about five minutes, when she took him into a room, told him to be seated there and the doctor would be in; that he came in in about three or four minutes and shook hands with Mr. Parkinson. Mr. Parkinson introduced himself, told the Doctor that he wanted to get this refilled and handed him an empty bottle.

He told the Doctor he was leaving to go on a ship right away and wanted to have the prescrip-

(Testimony of Hazen S. Parkinson.)

tion refilled. The Doctor asked him how old he was and he said 65 years old. The Doctor asked Mr. Parkinson if he was married and he replied no. The Doctor asked what he was taking them for and Mr. Parkinson replied that he thought that they sort of tightened up his muscles and toned up his system. The doctor gave him a glass and told him to give him a urine sample. The doctor left the room and was gone about three minutes. The doctor said maybe he had better have an examination and he examined his rectum, which examination consumed not over 30 seconds. The doctor asked how many he wanted and Parkinson said he wanted the bottle filled. The doctor replied, "That will be expensive," and Parkinson said that he was going on a ship and didn't want to run out. That he was going on shuttle runs, [763] which would consume about a year, and "You know on a ship there are several staying in a room and, whenever you take a pill, some of the others will want one, too, and you have got to give it to them." The doctor then wrote out the prescription in Mr. Parkinson's presence and handed it to him, for 500 Metandren Linguets, 5 milligrams, directions, one a day. Parkinson paid him \$5.00. The doctor asked Parkinson how many he took per day and Parkinson replied that he sometimes took two or three, depending upon how he felt. The doctor said, "Why don't you just take one?" and Parkinson said, "Well, I can just take one if you say so. You are the doctor." Then Dr. Heckel said, "You can take

(Testimony of Hazen S. Parkinson.)

one or two a day for a week or two and then drop back to one a day.” Nothing was said to Mr. Parkinson by the doctor about that the taking of this product might affect his sterility or fertility or that, if any other men on the ship might take it, it might accelerate the growth of a cancer of the prostate or affect their fertility.

I also offer to prove that Mr. Parkinson called on several doctors, on the dates mentioned on certain prescriptions, throughout parts of Los Angeles County, and talked at random; that in each instance he went into the doctor's office, told the doctor that he wanted this same bottle, the one he used when he saw Dr. Heckel, refilled, and asked for a prescription; that in each instance he received a prescription for [764] these linguets and on no occasion was anything said to Mr. Parkinson about sterility or fertility or cancer of the prostate, nor did any of the doctors lay a hand on him, and he did not call on any doctor who turned him down on the request for a prescription.

The doctors that would be subject to Mr. Parkinson's testimony in that regard would be Dr. G. G. Ferbryck, M. D., 516 Professional Building, 117 East 8th Street, Long Beach, California, who wrote out a prescription for Metandren Linguets, one a.m. and p.m., and the date was June 29, 1949; Dr. Wayne P. Hanson, in the same building, on June 30, 1949, wrote out a prescription for 500 10-milligram Metandren Linguets, directions, one linguet daily; that he also called on Dr. George D. Stilson

(Testimony of Hazen S. Parkinson.)

and Dr. Milo Ellik, together in the same office, 511 Professional Building, 117 East 8th Street, Long Beach, on June 30, and received a prescription from Dr. Ellik for 500 Metandren Linguets, directions, as directed; that he called on Dr. Raymond W. Kelso on June 31, 1949, the doctor's address being 117 East 8th Street, Long Beach, who wrote out a prescription for 250 10-milligram Metandren Linguets, with directions, dissolve one on tongue each day; that he called on George B. Hanson, M. D., 716 Professional Building, 117 East 8th Street, Long Beach, on June 30, 1949, received a prescription for 250 Metandren Linguets, 10 milligrams, directions, one per day; that he [765] called on Dr. H. F. Gramlich on June 30, 1949, address, 117 East 8th Street, Long Beach, and received a prescription for one bottle of Metandren Linguets, directions, as directed; that he called on Dr. P. W. Prince of the Bishop Clinic Staff, 117 East 8th Street, Long Beach, on June 30, 1949, and received a prescription for 250 10-milligram Metandren Linguets, directions, I guess it is, one daily, dissolve in mouth; that he called on Dr. L. L. Wiltse, 714 Professional Building, 117 East 8th Street, Long Beach, on June 30, 1949, and received a prescription for 500 Metandren Linguets, directions, take as directed; that he called on Dr. Marvin R. Lauer, 829 East Compton Boulevard, Compton, California, on July 2, 1949, and received a prescription for 500 Metandren Linguets, 10 milligrams, directions, use as directed; that he called on Dr. Francis J. Ort,

(Testimony of Hazen S. Parkinson.)

107 North Santa Fe Avenue, Compton, California, on July 2, 1949, and received a prescription for 500 Metandren Linguets, directions, two daily; that he called on Dr. L. C. Lowe, 706 South Hill Street, Los Angeles, on July 1, 1949, and obtained a prescription for 500 Metandren Linguets, 10 milligrams, directions, as directed; that he called on Dr. Glenn E. Jones, 403 West 8th Street, Los Angeles, on July 1, 1949, and received a prescription for 500 Metandren Linguets, 10 milligrams, directions, one or two per day; that he called upon Dr. R. L. Byron, 1015 Chapman Building, 756 South Broadway, [766] Los Angeles, on July 1, 1949, and received a prescription for 500 Metandren Linguets, 10 milligrams, directions, one as directed.

The Court: The offer of proof is refused. You may file those prescriptions. [767]

* * *

The Court: Exhibit J is received in evidence.

The Clerk: Exhibit J in evidence.

* * *

Q. (By Mr. Elson): Let's start from here. You got into the office and now will you state, please, what happened?

A. I asked the nurse for Dr. Heckel and she said, "Be seated a minute and I will go in and see the Doctor."

She returned in a minute or two and said, "Be seated," or "Stay seated and the Doctor will be back." In about three minutes she took me into

(Testimony of Hazen S. Parkinson.)

another room and said, "The Doctor will come in here." In about three minutes he came in. We shook hands and I introduced myself and told him what I wanted. I told him I wanted to get this bottle refilled——

Q. What a minute. Did you have a bottle with you? A. Yes, sir.

Q. I have a bottle with a label on it, "Metandren Linguets, 500," with some other writing on there. Is that the bottle that you presented at that time? [772] A. That is right.

Q. Go ahead, please.

A. And I showed him a prescription I had from Dr. Openshaw, that I had been taking by injection.

Q. For testosterone?

A. Yes; the same thing. I told him I was going on a ship and I was going to take them by mouth.

The Court: You showed him a prescription from some other doctor?

The Witness: Yes; Dr. Openshaw had given me a prescription to be given by injection, and he says, "When you get on the ship, you will need to take them by mouth," and I had the prescription to take them by mouth. [773]

And he said he had just been to Los Angeles on a trial and I says, "Well, what was wrong, was there anything wrong with them?"

And he said, "No," and he said, "There are some conditions where they might make a palpation of the prostate gland."

(Testimony of Hazen S. Parkinson.)

And I said, "Was there anything wrong with taking them, then, that is going to do me any danger? If there is, I don't want them."

He said, "Oh, no, I don't know as they will do you any damage, but we don't want them sold over the counter."

Q. (By Mr. Elson): Did the doctor examine you in any way? A. Yes.

Q. Tell me what he did.

A. He took the urine—he gave me a glass and told me to give him a urinal sample and he examined my prostate.

Q. He put his finger up your rectum?

A. Yes.

Q. And did he write this prescription in your presence? A. Yes.

Q. And was there anything said by the doctor to you on the subject of fertility or sterility?

A. No.

Q. Did you, in your discussion with the doctor, discuss rooming with other men on a ship? [774]

A. Yes.

Q. Will you tell us what the subject of the conversation was?

A. Well, when I told him I wanted the 500, he said, "That is quite a few." He said, "They are expensive, too."

I said, "Well, if you have ever been on a ship, there are three or four men to a room and every time you take a pill, someone else wants one."

He laughed. He said, "That is right." So he

(Testimony of Hazen S. Parkinson.)

made them at 500. He said, "How do you take them?"

I said, "I take one or two a day mostly and according to how I feel."

He said, "I will put down here 'one a day,' and take them the way you feel, the way you have taken them before."

I said, "Okay," and I said, "They won't do me any damage?" He said, "No."

Q. (By Mr. Elson): All right. Now, how long a time was consumed, approximately, from the time you walked into the doctor's office until the time you walked out with the prescription?

A. I would say five or six minutes.

Mr. Elson: Cross-examine.

I would like to offer this bottle into evidence.

Mr. Neukom: No objection.

Mr. Elson: As defendants' exhibit next in order. [775]

The Clerk: That will be Defendants' Exhibit K, the bottle.

(The article referred to was marked Defendants' Exhibit K and received in evidence.)

Mr. Elson: And these other prescriptions that were included in, let us say, my second offer of proof. Would you mark these for identification, Mr. Clerk, as one composite exhibit, with the receipts attached to the ones in which receipts were obtained?

The Court: Yes.

The Clerk: Yes. That will be Defendants' Ex-

(Testimony of Hazen S. Parkinson.)

hibit L, for identification, group of receipts. Those are receipts and prescriptions.

(The documents referred to were marked Defendants' Exhibit L for identification.)

Cross-Examination

By Mr. Danielson:

Q. How old are you, Mr. Parkinson?

A. Sixty-five.

Q. As a matter of fact, you told Dr. Heckel you were 72, didn't you?

A. No, I did not. I showed him my merchant marine card, that says 65 right on it. I handed him that (indicating card).

Q. Where were you born? [776]

A. Franklin, Idaho.

Q. Where? A. Franklin, Idaho.

Q. And when? A. April 1, 1884.

Q. Who referred you to Dr. Heckel?

A. I told him that a man in a garage at the hotel where we stayed did.

Q. Who actually referred you to Dr. Heckel?

A. Why, my son.

Q. That is Mr. Parkinson here——

A. Yes.

Q. ——a defendant in one of these cases?

A. Yes, sir.

Q. You say you arrived in Chicago about June 26th? A. Yes, sir.

Q. Where were you just prior to that time?

A. You mean the day before?

(Testimony of Hazen S. Parkinson.)

Q. Well, two or three days before, had you just come in from Salt Lake City?

A. No. I was in Long Beach.

Q. From Long Beach, you came in?

A. Yes.

Q. What was the purpose of your trip to Chicago?

A. To get a prescription from Dr. Heckel. [777]

Q. That was you entire purpose of your trip from Long Beach, from the Pacific Coast to the city of Chicago?

A. Yes, sir, that was my entire purpose.

Q. Sir? A. That was the entire purpose.

Q. Who paid your expenses on that trip?

A. My son.

Q. Again referring to Allan Parkinson, a defendant in one of these cases? A. Yes, sir.

Q. When did you see Dr. Openshaw last, Mr. Parkinson?

A. It would be on the 25th of June.

Q. That is at Salt Lake City? A. Yes, sir.

Q. On the 25th of June? A. Yes, sir.

Q. And your son was present at that time, is that correct? A. Yes, sir.

Q. Is that not correct?

A. Yes, that is right.

Q. Did you receive any testosterone from Dr. Openshaw at that time?

A. I received a prescription, but no——

Q. You received a prescription at that time?

A. Yes, sir.

(Testimony of Hazen S. Parkinson.)

Q. Is that the prescription you showed to Dr. Heckel at Chicago? A. That is right.

Q. As a matter of fact, had you been taking testosterone for a couple of years?

A. I had taken some my son had given me.

Q. Had you been receiving any such treatment from Dr. Openshaw at Salt Lake City?

A. No, sir.

Q. When had you last seen him prior to June 25th?

A. I think I was in Salt Lake last fall and I saw him.

Q. When you are in Salt Lake, he is your regular doctor, is that correct? A. That is right.

Q. Are you a sailor, Mr. Parkinson?

A. I belong to the Coast Guard. That is a sailor, yes.

Q. Well, are you active as such?

A. Not right now.

Q. How long has it been since you were an active sea-going sailor?

A. The last time I was on a ship was just before the strike. It would be in September, I believe it was '47.

Q. That is nearly two years ago? [779]

A. Yes, they had a strike, then, and I got off and I haven't been on since.

Q. Then, actually, you are not presently a sailor?

A. Yes, I am always a sailor.

Q. But you are not an active sailor, anymore?

A. I am not an active sailor anymore.

(Testimony of Hazen S. Parkinson.)

Q. But you did tell Dr. Heckel that you were?

A. No. I told him I was trying to go to sea.

Q. And you told Dr. Heckel that you were gone from this country for long periods of time?

A. Yes.

Q. As a matter of fact, you have not been gone from this country for almost two years?

A. That is right, but I told him I would be gone for long periods when I got on a ship.

Q. You likewise told Dr. Heckel that you wanted enough testosterone for a year, is that correct?

A. That is correct.

Q. And not only for yourself, but for such other sailors that might want a pill now and then?

A. That might want them, yes.

Q. As a matter of fact, if you wanted to, you could buy testosterone from your son, couldn't you?

A. Oh, yes, yes.

Q. Wholesale. Your only purpose in going to Chicago [780] was just to get this prescription?

A. That is right.

Q. You told Dr. Heckel, did you not, that your son's doctor had given you a prescription for methyl testosterone? A. That is right.

Q. And that you had been taking those under your doctor's orders for the past several years?

A. That is right.

Q. And this was not true?

A. Not several years. Maybe two years.

Q. And this was not true, was it?

A. No, sir.

(Testimony of Hazen S. Parkinson.)

Q. And when Dr. Heckel gave you the prescription, he told you, did he not, requested, advised you to report to your physician at regular intervals?

A. Absolutely not. I was going on a ship. I couldn't swim over.

Q. They usually have doctors on a ship, don't they, the Coast Guard?

A. No, he didn't tell me anything about my doctor.

Q. Specifically, did he advise you to report to your physician at regular intervals?

A. He did not. He did not.

Mr. Danielson: No further questions.

Mr. Elson: That is all. [781]

* * *

Mr. Elson: May it please the court, Mr. Neukom, Mr. Danielson and myself have had a little discussion during the recess and I think that we can cover the balance of the case of Mr. Parkinson by a stipulation.

* * *

Mr. Elson: Yes. (Continuing) In connection with the Parkinson case, No. 20642, Criminal, that the pamphlet entitled "The Male Hormone," Government's Exhibit 1-A in Count 1, 2-A in Count 2, 3-A in Count 3 and 4-A in Count 4—— [782]

* * *

Mr. Elson: (Continuing) This booklet entitled "Male Sex Hormone Therapy," published by Roche-Organon, Inc., was [783] used as the source of ma-

terial in the preparation of both of those, the pamphlets that I have referred to as exhibits in the case;—

Mr. Danielson: That Mr. Parkinson would so testify.

Mr. Elson: —that Mr. Parkinson would so testify.

The Court: That pamphlets you refer to are “The Story of Hormones”——

Mr. Elson: Yes, that is one of them. There is a duplication here. For instance, I am looking at Government’s Exhibit 1-A in Count 1, and here is the pamphlet, here is the full pamphlet itself, that is 1.

Now, in connection with this Exhibit 3-B in Count 3, which is entitled “The Story of Hormones,” that those two pamphlets, that the booklet entitled “Male Sex Hormone Therapy,” published by Roche-Organon, Inc., was used as a source of material in the preparation of both of those pamphlets, and that Mr. Allan Parkinson would so testify.

Mr. Danielson: The government will stipulate that Mr. Allan Parkinson would testify that the described pamphlet “Male Sex Hormone Therapy” was used by him as source of material in preparation of these pamphlets.

Mr. Elson: That is correct.

Mr. Danielson: That is agreeable to the government.

The Court: These pamphlets were prepared by Parkinson of Hudson Products Company? [784]

Mr. Elson: Yes.

The Court: Yes. I see.

Mr. Elson: There are just the two pamphlets. "The Male Hormone" pamphlet is the small one here.

The Court: Is this in evidence here?

Mr. Elson: No. It is not, but I am going to offer it.

Mr. Danielson: Exhibits 1-A, 2-A, 3-A and 4-A are identical pamphlets.

Mr. Elson: They are identical pamphlets.

And the government and the defendant Parkinson stipulate accordingly?

Mr. Danielson: The government will so stipulate.

Mr. Elson: And so does the defendant Parkinson, and I therefore now offer into evidence the book that I have just referred to, "Male Sex Hormone Therapy," published by Roche-Organon, Inc., as the defendant Parkinson's next exhibit in order.

The Clerk: What exhibit number would that be, Mr. Elson?

Mr. Elson: I don't know.

Mr. Sturzenacker: That would be "A" for Parkinson.

Mr. Danielson: It would be "A" for Parkinson.

Mr. Elson: Yes, that is right.

The Clerk: That is in Case No. 20642, Defendant's Exhibit A in evidence.

Mr. Elson: Just a moment. [785]

The defense in Case 20596, Criminal, and the defendant in Case No. 20642, Criminal, rest.

Mr. Neukom: That is in both the Clemens and Parkinson cases. [786]

JOHN R. WINCH

called as a witness by and on behalf of the plaintiff, having been first duly sworn, was examined and testified as follows in reguttal: [788]

The Clerk: Your full name?

A. John R. Winch.

Direct Examination

By Mr. Danielson:

Q. Mr. Winch, what is your occupation?

A. I am inspector of the Food and Drug Administration, stationed at Phoenix, Arizona.

Q. And were you so employed on or about November 1, 1947? A. I was.

Q. Now, in the course of your employment, on or about that date did you have occasion to receive a parcel from Martin A. Clemens or the M. A. Clemens Pharmacy, Los Angeles? A. I did.

Q. Did you make a record, if any, of the nature of that parcel that you received?

A. I did, at that time. I made the record on November 1st. I have it here. [789]

Q. You have such a record with you?

A. Yes.

Q. What does that record include, in general terms?

A. That is a record which is a collection report that we fill out for every sample. We fill out one such form for every sample that we obtain or collect.

Q. Is that recorded in the regular course of your business? A. It is.

(Testimony of John R. Winch.)

Q. As an official business? A. Yes, sir.

Q. Does that include the wrapping of the parcel?

A. That includes the labeling, marker, or other description of the parcel, how much it contains, what there is of it and what I do with it.

Mr. Elson: What count is this?

Mr. Danielson: This is count 1, Mr. Elson.

If your Honor please, the purpose of this inquiry is to establish precisely what labeling accompanied the shipments which are the subjects of the several counts of the information filed against Mr. Clemens and the El-O-Pathic Pharmacy. There has been testimony before the court by Mr. Clemens to the effect that in each of these shipments labeling in addition to that which has been made the subject of the stipulation was included with the shipments, such as brochures [790] from the manufactures.

Q. Mr. Winch, I show you Government's Exhibits 1 and 1-A, which are a label and a pamphlet, Exhibit 1-A being a pamphlet entitled "Male and Female Sex Hormones," and ask you if you recognize them. A. I do.

Q. Does your name or initials appear thereon?

A. I have written on them the sample number, the date that I received the sample, and my initials.

Q. Now, does that sample number compare with the numbers on the report that you have before you?

A. That does.

Q. Are the labelings which are reported on that collection report?

(Testimony of John R. Winch.)

A. They are the labeling which is described in that collection report.

Q. Now, do you recall receiving this shipment?

A. I do.

Q. What labeling did accompany the shipment?

A. The labeling that accompanied the shipment, the material consisted of one carton, the carton contained one circular entitled "The Male and Female Sex Hormones," and it also contained one unlabeled clear plastic container of five tablets. This was the label that was on the carton.

Q. You are referring to Government's Exhibit 1? [791]

A. Government's Exhibit 1 is the label that was on the carton as I received it.

Government's Exhibit 1-A is the circular that had been included with that carton.

Q. Now, Mr. Winch, were there any other labels or pamphlets or literature included in this shipment?

A. There were none.

Q. I particularly refer your attention to Defendant's Exhibit D, a brochure entitled "Oral Androgenic Therapy," and ask you whether it or a similar brochure accompanied this shipment.

A. No.

Q. I likewise invite your attention to Defendants' Exhibits "C" captioned "Oral Estrogen Therapy," and "A" entitled "Menformon Dosules," and ask you whether either of them or any copy of them accompanied this shipment.

A. No.

Q. This collection report, No. 30046-K, was made

(Testimony of John R. Winch.)

by you as you say in the regular course of your business.

A. That is correct, on the same day on which I received the carton through the mail.

Q. And you knew it to be accurate and correct at that time? A. That is right. [792]

* * *

The Court: I suggest this is merely the formal report submitted to this officer's superior as to his conduct and the happenings at that time and place.

Mr. Neukom: That is right.

Mr. Danielson: That is what it is, is it, Mr. Witness?

The Witness: Yes. I have a copy of it.

Mr. Elson: No, there isn't anything in that report or any of the documents that I have looked at, your Honor—it is a typical agent's report.

The Court: Well, to round out the record, let it go in as an exhibit.

Q. (By Mr. Danielson): Now, Mr. Winch, were you likewise employed in the same capacity on or about October 30, 1947? A. Yes.

Q. And did you on that date receive a package from the El-O-Pathic Pharmacy, Inc., Los Angeles, in Phoenix, Arizona?

A. I received the package that you are referring to on November 1st, according to my collection report, the document I filled out.

Q. That is from the El-O-Pathic Pharmacy?

A. From the El-O-Pathic Pharmacy, 1109½ North Western Avenue.

(Testimony of John R. Winch.)

Q. Los Angeles, California?

A. Yes, marked "Hollywood 27" here.

Q. Did you make a record of the labeling that accompanied that package? A. I did. [794]

Q. And what was the description of the contents of that package?

A. That package contained one carton, which contained one small envelope of five tablets, a circular and an envelope that had the return address of the El-O-Pathic Pharmacy. That is the contents.

Q. I invite your attention to Government's Exhibit 2, count 2, which is before you, and ask you if that label was included there.

A. This was the label that was on the carton that was contained in the package.

Q. I invite your attention to Government's Exhibit 2-A, before you, and ask you whether that label was included.

A. This is the circular that was included in that package.

Q. Were there any other labels or circulars included in that package? A. There were none.

Q. I particularly invite your attention to Defendants' Exhibits A, C and D, which are before you. Would you pick them up and show them to the court, if you please, Mr. Winch?

The Court. Yes.

The Witness: This is A. This one is D.

The Court: Yes.

The Witness: This one is C, your Honor.

The Court: Yes. [795]

(Testimony of John R. Winch.)

Q. (By Mr. Danielson): Were any of them or any copy of them included in this shipment?

A. No.

Mr. Danielson: Mr. Elson, are you willing to stipulate?

Mr. Neukom: To shorten the time.

Mr. Elson: On the others?

Mr. Neukom: Yes.

Mr. Elson: Sure.

Mr. Danielson: I believe, your Honor, counsel will now stipulate that as to these counts 3, 4, 5, 6, 7, 8 and 9, that the labeling received——

The Court: 3, 4?

Mr. Danielson: Up through 9, 9 inclusive.

The Court: Now, 3 was apparently handled by this witness; 4 by Brandenburg.

Mr. Neukom: We have him here.

Mr. Danielson: We have these witnesses here, your Honor. This is merely to shorten the time.

Mr. Elson: This is merely to shorten the time, because I know what they are going to testify to and there is no use of taking up the time.

The Court: Yes.

Mr. Neukom: As to all counts, your Honor.

The Court: 3, 4, 5, 6, down to and including 9?

Mr. Danielson: Including all of the counts, your Honor, [796] that would be up to and including 14.

The Court: Yes. Now, state your stipulation.

Mr. Danielson: Is that agreeable?

Mr. Neukom: I will make the stipulation:

The stipulation would be, your Honor, that as to

(Testimony of John R. Winch.)

all counts, either this witness or the other named government agents, or other individuals who are consignees, would testify, if called to the stand, that the only documents or articles they received in the various counts enumerated were those accompanying or set forth in the stipulation, and that they did not include Defendants' Exhibits C, D and A. That would be their testimony.

The Court: When you refer to the stipulation, you mean the one entered into as of June 15, 1949?

Mr. Danielson: In the Clemens case.

Mr. Neukom: Wait a minute. I will find out.

The Court: Yes, case No. 20596.

Mr. Neukom: June 15, 1949.

The Court: Yes, I get it. I think it is clear in the record.

Mr. Neukom: You so agree?

Mr. Elson: Yes, I do.

Mr. Neukom: As to both cases, Parkinson—oh, no; as to the Clemens case.

Mr. Elson: As to the Clemens case. [797]

Mr. Neukom: Yes.

Mr. Elson: Yes, I so agree.

Mr. Neukom: And as to counts 1 to 9, inclusive—and, if your Honor does not understand me, please stop me, because I am not embarrassed——

The Court: I hear you and understand you very well.

Mr. Neukom: As to counts 1 to 9, inclusive, the government will further stipulate that the products thereby obtained were the result of government

(Testimony of John R. Winch.)

agents operating in their official capacity writing in for the product, obtaining it in their official capacity, and that they did not actually use it or did not want to use it, but that they were just writing for it in the performance of their duty.

The Court: Yes.

Mr. Neukom: Is that satisfactory?

Mr. Elson: That is satisfactory.

Now, as to the Parkinson case.

Mr. Neukom: Now, in the other case, your Honor, the Parkinson case, we will make a similar stipulation in that case, only as to count 3——

Mr. Elson: 3 and 4, counts 3 and 4, the stipulation covering, however, only this: that the consignee in counts 3 and 4 were government agents.

Mr. Neukom: Just one.

Mr. Elson: Yes, but it was the same one in each count. [798]

Mr. Neukom: Yes.

Mr. Elson (Continuing): ——was a government agent who wrote in for the product, in count 3, from Seattle, and in count 4 from Seattle to Mr. Parkinson's place of business in Long Beach, ordering the shipment that was shipped; that the government agent ordered it for the purposes of obtaining evidence and in the performance of his duty as an officer, and that he did not use the product involved in either count for his own use or otherwise than as evidence in the case.

Mr. Neukom: That is right. [799]

Mr. Neukom: I don't think you have any questions, have you?

Mr. Elson: I have no questions. [800]

* * *

Rebuttal

Mr. Danielson: If your Honor please, in the interest of saving time, it has been agreed between counsel for the government and for the defendants as to what Dr. Heckel would testify to if he were recalled. With your permission, I would like to read that into the record.

It is stipulated and agreed that, if Dr. Norris J. Heckel were present and sworn as a witness to testify, and did so testify, he would testify that, on June 27, 1949, a [803] Mr. Parkinson came to his office in Chicago and stated that he had been referred to by a former patient. Parkinson said that he was 72 years of age, a sailor by occupation and gone from the country for long periods of time; that he was in Chicago as a transient; that his doctor in Salt Lake City had been giving him a prescription for methyl testosterone and that he had been taking this drug under his doctor's direction for the past several years; that he was leaving the country and needed about a year's supply of testosterone and requested a prescription for a year's supply. He showed Dr. Heckel a prescription for testosterone issued by another doctor. Dr. Heckel then made a physical examination of Parkinson, which included a urine analysis and a rectal examination of the prostate and found no contraindication to the use

of testosterone; he found that Parkinson's prostate was of normal size, shape and consistency, with no evidence of prostatitis; and that he then renewed Parkinson's prescription for methyl testosterone linguets and advised him to report to his physician at regular intervals.

Mr. Elson: That is so stipulated, that, if Dr. Heckel were here, he would so testify.

Mr. Danielson: Thank you.

The Court: Very well.

Mr. Danielson: Dr. Terrill, please. [804]

ELWYN E. TERRILL, M.D.

called as a witness for the government in rebuttal, being first duly sworn, testified as follows:

The Clerk: Your full name?

The Witness: Dr. Elwyn E. Terrill (spelling same).

The Clerk: Which case is this?

Mr. Danielson: This is the El-O-Pathic and Parkinson; all of the cases. It is No. -596 and as it applies in the other case.

Mr. Elson: All right.

Direct Examination

By Mr. Danielson:

Q. Dr. Terrill, you are an M.D., is that correct?

A. Yes; I am.

Q. Where do your practice, Dr. Terrill?

A. 1401 South Hope Street, Los Angeles.

Q. From what schools were you graduated, Doctor?

A. I graduated from Loma Linda.

(Testimony of Elwyn E. Terrill, M.D.)

Q. Is that where you received your M. D.?

A. Yes.

Q. In what year? A. In 1927.

Q. Did you have some connection with the College of Medical Evangelists?

A. That is the College of Medical Evangelists.

Q. Are you a member of any medical societies, Doctor?

A. I am a member of the Los Angeles County Medical Association, the State and the American Medical Association. I am a general practitioner and belong to that section of the County Medical Society and, also, the Academy of General Practice.

Q. Doctor, apparently you have been in general practice here for a little better than 20 years, is that correct? A. Yes, sir.

Q. Doctor, in the course of your practice, do you ever have occasion to prescribe testosterone?

A. I prescribe testosterone occasionally.

Q. Under what circumstances do you use testosterone?

A. Well, for a very limited field of conditions; usually a hypogonadism, if it is due to glandular origin.

Q. What precautions, if any, do you take prior to using testosterone?

A. I take a very careful history on all of my patients and always examine them completely.

Q. Does that include an examination of the prostate, Doctor?

(Testimony of Elwyn E. Terrill, M.D.)

A. Yes; in all male patients it does, especially if testosterone is to be considered.

Q. Why do you give this examination?

A. The examination of the prostate? [806]

Q. Yes, Doctor.

A. Well, because of the danger, as it is commonly believed today, of giving testosterone where there is any question of a carcinoma of the prostate.

Q. Doctor, you are a member of several medical societies and I presume you have discussions on medical subjects with other doctors from time to time, is that not correct? A. Yes, sir.

Q. Do you have an opinion as to whether the precautionary measures you have taken are general in the medical profession?

A. Among my circle of friends, I know they are.

Q. You do not know, among your circle of friends, of any promiscuous use of testosterone?

A. No; I do not know of any.

Q. That is the doctors among your friends?

A. Yes.

Mr. Danielson: No further examination. [807]

Cross-Examination

By Mr. Elson:

Q. Doctor, I am going to show you the Defendants' Exhibit L for identification, which consists of a number of prescriptions for linguets, and these prescriptions are by several doctors. They have been pinned together. I am going to ask you to look at those and tell me if you know or are ac-

(Testimony of Elwyn E. Terrill, M.D.)

quainted with any of the doctors whose names appear on there.

(The witness examines said exhibit.)

A. I recognize two names.

Q. Who are they, please?

A. Glenn Jones, 403 West Eighth Street.

Q. Long Beach?

A. No. Los Angeles. Isn't it Los Angeles?

Q. Yes, that is right.

A. And the other one, Marvin S. Lauer.

Q. And his address? A. Campton.

Q. Do you know of the Bishop Clinic staff at Long Beach?

A. No. I I know of it. I knew the name, but I don't know——

Q. Do you know Dr. Lauer, and who is the other?

A. Glenn Jones. I haven't seen Dr. Lauer for 20 years. [808]

Q. Now, if I told you that a man of the age of about 65 years called on each of the doctors whose names appear on the prescription pads that you have examined and told them that he wanted a refill of this bottle of Metandren Linguets, which is Defendants' Exhibit K, 500 Metandren Linguets, and that each one of those doctors wrote a prescription for this gentleman without laying a hand upon him, would that change your opinion in any respect as to the ordinary course of practice pursued by doctors in this locality in the use of testosterone?

A. May I ask you a question before I answer, so I get your question straight?

(Testimony of Elwyn E. Terrill, M.D.)

Q. Go ahead.

A. He came in and just asked for a refill on this prescription?

Q. That is correct.

A. And it was given without any examination?

Q. Without them laying a hand upon him.

A. I wouldn't think that was **general practice in** my community, at least not among my associates.

The Court: Where did you say you practiced?

A. 1401 South Hope Street, Los Angeles.

Q. (By Mr. Elson): Your address is 1401 South Hope? A. Yes, sir.

Q. And that is the same building, is it not, in which [809] the Food and Drug Administration's offices are located? A. Yes, it is.

Q. Do you do any work for the Food and Drug Administration?

A. I met the first man of that group I have ever met in my life just yesterday.

Mr. Elson: I haven't anything further.

Redirect Examination

By Mr. Danielson:

Q. Doctor, do you have any official connection with the Food and Drug Administration?

A. None whatever.

Q. And that building in which you are located, so far as you know, is a private building, is it not?

A. It was until the war I believe exclusively for doctors.

Mr. Danielson: No further questions. Thank you very much, Dr. Terrill.

* * *

Mr. Danielson: If the court please, in an effort to conserve time, again, it is agreeable between counsel for the government and counsel for the defense that the government could produce additional general practitioners who would [810] merely serve to corroborate the testimony of Dr. Terrill, and likewise, that the defense could produce additional general practitioners who would tend to corroborate their general practitioners, and we are willing to stipulate as to that fact and to eliminate further testimony of this nature.

The Court: I think that is very reasonable. [811]

* * *

Miss Nute, please.

JEANNETTE M. NUTE

called as a witness for the government in rebuttal, being first duly sworn, testified as follows:

The Clerk: Your full name?

The Witness: Jeannette M. Nute.

Direct Examination

By Mr. Danielson:

Q. Miss Nute, what is your occupation, please?

A. I am a registered nurse.

Q. Where are you employed? [814]

A. I am employed by Dr. Elmer Belt at 1893 Wilshire Boulevard, in Los Angeles.

(Testimony of Jeannette M. Nute.)

Q. Were you so employed on June 24, 1949?

A. Yes, sir.

Q. Miss Nute, I direct your attention to a Mr. Parkinson seated at the other table there, the second gentleman from the end.

A. Yes, sir.

Q. Do you recognize him?

A. Yes, sir.

Q. Did you have occasion to see him on June 24, 1949?

A. Yes, sir; I did.

Q. And that was at the Belt Urologic Group, is that correct?

A. Yes, sir.

Q. What were your duties there on that day?

A. I am a nurse receptionist for Dr. Belt and as such I take care of the patients as they come in to the office. I take their names down. If they are new patients, I place them in an office and, if they are regular patients, I direct them to the reception room. And, as the patients leave the office, I make appointments for them and give them the prescriptions ordered by the doctor and, of course, some of them make payments.

Q. Did you make any record of the time of arrival of [815] Mr. Parkinson at the clinic?

A. No. My assistant, Miss Kathleen O'Hare, or my associate, did.

Q. Was that made——

A. As Mr. Parkinson came in.

Q. That was made in the regular course of business there, is that correct?

A. Yes, sir.

Q. Do you have that record?

A. Yes, sir; I do.

Q. What time was that arrival?

(Testimony of Jeannette M. Nute.)

A. Mr. Parkinson arrived at our office at 9:40, June 24th.

Q. 9:40 a.m.? A. Yes, sir.

Q. Do you have any record indicating how long he remained in your office? A. Yes, sir; I do.

Q. Will you tell us what records you have of the various times he was present in your office on the morning of June 24th?

A. As the patient comes into the office, a blue slip, such as this, is made out, indicating the time the patient comes in. Mr. Parkinson was a new patient. So, therefore, he was placed in one of the doctor's offices in the building, [816] which in this particular case was Dr. Ebert's office, which is No. 2. He was placed in Dr. Ebert's office at 9:45.

Q. How long did he remain there, according to your records?

A. According to our records, he remained there until 10 minutes after 10:00.

Q. And what was done with him then?

A. A history was taken between that time.

Q. Where did he go after 10:10, according to your records?

A. According to our records, he was taken to Room 15.

Q. How long did he remain there, according to your records?

A. According to our records, until 10 minutes of 11:00.

Q. Who would have seen him in Room 15, if you know?

(Testimony of Jeannette M. Nute.)

A. The technician, Mr. Joseph Hansel, I believe, instructed the patient to undress, and Dr. Belt then went in and gave a physical examination.

Q. Do you have any record of when he left the Group on completion of his visit that morning?

A. No, sir; I have not.

Q. But it would have been at 10:50 or subsequent to that time? A. Yes, sir. [817]

Mr. Danielson: No further questions.

Mr. Elson: May I see your record sheet?

The Witness: Yes, sir.

* * *

Mr. Danielson: Dr. Elmer Belt, please.

ELMER BELT, M.D.

a witness for the government in rebuttal, being previously duly sworn, was recalled and testified as follows:

The Court: You have been sworn.

Direct Examination

By Mr. Danielson:

Q. Dr. Belt, to clear up the record, there has been some confusion here as to the size of a normal prostate. You have had occasion to observe them on many occasions, is that right? A. Yes, sir.

Q. How large, Doctor, is a normal prostate in a normal male adult?

A. 19 grams. There are 30 grams in an ounce and you can figure about the size from that.

(Testimony of Elmer Belt, M.D.)

Q. This is a spheroid of what diameter, more or less? [818]

A. That is about the size that I am illustrating.

The Court: That is, a dollar?

The Witness: Oh, smaller than a dollar. I don't know how big a dollar looks to you, Judge. I brought some——

Q. (By Mr. Danielson): Do you have a prostate with you, Doctor?

A. Yes. If the Judge would like to see them, I have brought up samples of prostates that are normal in size and hypertrophied due to benign hypertrophy and hypertrophied due to cancer.

Q. Could we see a normal one, Doctor?

A. I don't know which jar contains the normal but they are stacked up there if you would like to see them.

Mr. Elson: You don't intend to introduce them into evidence, do you?

Mr. Danielson: No, Mr. Elson.

The Witness: This is a portion of a bladder and prostate which has been removed because of a cancer of the bladder. The cancer is where that section has been taken out. The prostate is the part you see from this point down, and on this side of the specimen only half of it is specimen because the specimen is cut exactly in two, which gives you the idea of the normal size of the prostate. This is a triangular area here, the top of which constitutes the floor of the bladder and the bottom of which is the pointed structure [819] below.

(Testimony of Elmer Belt, M.D.)

The Court: I have seen numerous illustrations of it.

The Witness: This is another specimen which shows the gland without having a slice through it, looking from the back. And, again, we have the trianugular structure, at the bottom of the bladder, of the prostate. Here it has a little window cut in it, from which this tumor growth was removed. From the anterior surface, the structure looks like that.

Q. (By Mr. Danielson): Doctor, what is this?

A. That is the tumor growth, the benign growth, which has been removed from the inside of the prostate.

The Court: I can see the patient died.

The Witness: Yes. That is an autopsy. [820]

* * *

The Court: Doctor, I would like to know just that part of the prostate which may be felt. It is complicated. All of it?

A. One feels the prostate from the posterior surface, the back surface. If you recall that triangle that had the V-shaped notch cut in it, in feeling the prostate, the finger passes over that surface. That surface would be covered by a thin membrane about half as thick as the thickness of your cheek, if you put one finger inside your mouth and the other outside. The rectal wall is about half that thickness. The [821] finger passing over that soft rectal wall detects the contour of the prostate which lies beneath it.

(Testimony of Elmer Belt, M.D.)

Now, in the normal structure, the prostate is quite soft and hard lumps which are occurring within it abnormally can be felt fairly well throughout the whole structure of the gland, but the part that presents itself to the palpating finger is the back surface of that triangle that you saw.

Q. (By the Court): Well, suppose a growth was on the opposite side?

A. One can still feel it, but less distinctly. And if you wish to distinguish the surface of the gland the growth is on, you have to put a hard object like a sound in the channel which passes through the gland. Then, those contours along the posterior surface can be felt against the sound and the structures which are abnormally present in the anterior surface are held away from the finger by the sound, and you can tell where they are in that way. A sound is a metal instrument passed through the channel. But, without the sound, the urethra collapses down to nothingness and one can feel the whole structure of the prostate fairly clearly.

The Court: Well, the prostate surrounds the urethra?

A. Yes. The urethra passes directly through the substance of the gland in about its middle portion. In this specimen, the slice is made down through the prostate in a medial sagittal plane from before backward, so you can see the [822] course of a urethra passing through it, and you see also the relative proportion of the gland which lies behind and in front of the urethra, and you can see

(Testimony of Elmer Belt, M.D.)

that a finger pressing against this portion (indicating) will feel what is in here (indicating).

A finger pressing against the posterior portion will also detect what is present in the anterior.

Q. (By the Court): What is that projection out there (indicating)?

A. That is the vas deferens, which is carrying the sperm from the testicle to the seminal vesicle. In this specimen, the seminal vesicle has been dissected out, to show its exact position and the vas deferens is also shown and this kernel (indicating) is the prostate, and that area that you are looking at there is the region which is palpated most intimately by the examining finger. That (indicating) would be the posterior surface.

This (indicating) is the anterior, and you can see there (indicating) how the urethra passes directly through the prostate. That is the reason why a man becomes obstructed of urination, when the prostate enlarges, because it enlarges at the expense of that little space which is the urethra.

Q. (By the Court): Well, not altogether?

A. When an enlargement takes place, it takes place like that nodule of tissue is, it takes place in that manner and [823] the enlargement crowds in on the channel through which the patient must urinate.

Q. (By the Court): Well, in plain words, it is a general swelling of the prostate gland that enlarges both ways, inward, pressing on the urethra, and outward also, does it not?

(Testimony of Elmer Belt, M.D.)

A. That is right. But it is not a general swelling of the prostate. Enlargement is a specific thing that is happening. It is adenoma in the case of a benign hypertrophy, and an adenoma-carcenoma in the case of a malignant hypertrophy. And the benign prostate just crowds away the good prostatic tissue from the kernel of growing structure. In the case of a cancer, the cancer actually forms in the normal prostatic structure and it involves it as it advances.

The Court: Well, massage is used to reduce that enlargement in many instances, isn't it?

A. Prostatic massage has never, and does not now, reduce the size of a benign adenoma of the prostate. But if an inflammation in the prostate occurs and the prostate swells from accumulated products of inflammation, massage will sweep those products out and reduce the size of the prostate, but it doesn't reduce the size either of a cancer or a benign adenoma.

Q. (By the Court): Well, the benign adenoma is simply larger than the usual growth, isn't it? [824]

A. A benign adenoma is a growth, a nodular growth of a group of spheroids which occurs inside the prostate and produces a mass which blocks the channel.

Q. (By Mr. Danielson): Dr. Belt, I invite your attention to this gentleman sitting here, Mr. Parkinson. Now, you recognize him, do you?

A. Yes, indeed.

(Testimony of Elmer Belt, M.D.)

Q. Did you have occasion to treat Mr. Parkinson professionally on or about June 24, 1949?

A. Yes.

Q. Where was that examination, in your clinic here in Los Angeles? A. Yes, sir, in Room 15.

* * *

Mr. Danielson: I will rephrase that:

Q. Dr. Belt, did Mr. Parkinson tell you that he had been taking testosterone over a period of about two years?

A. Yes, sir. When I went into the room where Mr. Parkinson was, I reviewed the history which Dr. Satterlee in our [825] office had taken of him, briefly with him.

Q. And did he tell you that he had been taking testosterone propionate and Neo-Hombreol intramuscularly?

A. Yes, he said he had been receiving a weekly maintenance dose of 50 milligrams of testosterone Neo-Hombreol.

Mr. Elson: Just a minute. May I inquire—I notice the doctor is looking at something there—is that something that he wrote, or just what is it?

Q. (By Mr. Danielson): Doctor, you do have some notes there. Were they made in the usual course of your business? A. Yes.

Q. At or shortly after the time of the events which they purport to reflect?

A. At the moment.

Q. Were they made by you, or under your immediate supervision?

(Testimony of Elmer Belt, M.D.)

A. They were made under my immediate supervision and by me, both ways.

Mr. Elson: Well, then, if the court please, I have no objection of course to the doctor using the notes that he made for the purpose of refreshing his recollection. But, as to notes that were made by someone else, certainly that is hearsay. That is what the government has been complaining of here.

The Court: Well, if they are his business notes, made [826] in his presence at the time, he would know whether they were made accurately or not. I can't see hearsay in that.

Q. (By Mr. Danielson): Did Mr. Parkinson tell you, Doctor, that he had been taking 10 milligram tablets or linguets of testosterone three times daily?

A. He asked for such a prescription. I think he did not specifically state that he had been taking that. What he asked us for was these injections and he said he was going to San Francisco and he wished to have a maintenance dose of testosterone linguets to take with him.

* * *

Q. (By Mr. Danielson): Did Mr. Parkinson say who referred him to your office?

A. Yes. When I entered the room where Mr. Parkinson was, I asked him if Dr. Openshaw referred him to us and he said yes.

Q. Did he say why Dr. Openshaw had referred him to [827] you? A. Yes.

Q. Why was that?

(Testimony of Elmer Belt, M.D.)

A. He said that two years ago his testicles and penis had begun to atrophy and he became sexually impotent. He said that Dr. Openshaw of Salt Lake City had been treating him with a weekly maintenance dose of 50 milligrams of testosterone. He said that he had been away from Salt Lake City for three weeks and that his physician recommended that he come to us for this treatment. He said that he was leaving for San Francisco shortly.

Q. Did you make any general examination of Mr. Parkinson?

A. Yes, I made a complete examination of Mr. Parkinson, a complete general physical examination.

Q. What examination did you make, what steps did you take?

A. Mr. Parkinson took off his clothes and I examined him by first observing his general makeup, and his eyes, his pupils, his pharynx, his teeth, felt his thyroid, examined his thorax.

Q. By thorax, Doctor, you mean what?

A. Chest; I took his blood pressure, I determined his pulse rate and rhythm, I felt of his abdomen, I looked at his extremities, I tapped his reflexes, I examined his external [828] genitalia, I put a finger in his rectum and examined his prostate.

Q. As a result of that, did you find any contraindication for the use of testosterone?

A. No. I found no contraindication.

(Testimony of Elmer Belt, M.D.)

Q. Did you take any samples from Mr. Parkinson?

A. I instructed my technician to take a specimen of his blood, and he had already been instructed to void in three glasses, which he did, and that material was examined.

Q. And what was your purpose in requesting the blood sample to be taken?

A. The patient told me that he intended to return, and I wanted to know whether or not the acid or alkaline phosphatase had changed.

Q. And the purpose of that test would be what?

A. To see whether or not there had been any malignant change in his prostate. It had been unheard of in a man of 30, but it might occur.

Q. Now, did you give a prescription for the testosterone to Mr. Parkinson?

A. Yes, sir.

Q. Why did you do so, Doctor?

A. The patient told me that he was under the treatment of Dr. Openshaw of Salt Lake City, he said Dr. R. Openshaw, giving us the doctor's initial. I asked him that again, and asked him if Dr. Openshaw was giving him this material and he said he was.

And so I told Mr. Parkinson, before I began my examination, that the reason for doing it was that we examine people carefully who asked for this material or who were getting it, to be sure it wasn't doing them any harm. I did not wish, of course, to undermine Dr. Openshaw's authority with his patient. This man presented himself to me as a

(Testimony of Elmer Belt, M.D.)

transient actually under the care of another physician, and it would have been poor taste and poor policy and poor judgment on my part, as well as poor medicine, to interfere with the activities of his own physician.

Q. (By Mr. Danielson): Is that general professional practice?

A. Yes, with transients who are going to be in your office for only a short time, one would be extremely unwise in disputing the authority of his family doctor who is treating him constantly.

Q. In good professional medical practice, do you communicate such information to the patient's own doctor? A. Yes, at once.

Q. Did you do that in this case?

A. Yes. [830]

* * *

Q. (By Mr. Danielson): That is, you communicated with Dr. Openshaw at Salt Lake City, is that correct? A. Yes.

Q. Dr. Belt, I show you a copy of a letter which you have recently furnished to me. Is that a copy of the letter you furnished to Dr. Openshaw?

A. That is a carbon copy of it, yes.

Mr. Danielson: No further questions.

Cross-Examination

By Mr. Nelson:

Q. Do you have notes there, Doctor, from which you were reading?

(Testimony of Elmer Belt, M.D.)

A. Yes. Those are Dr. Satterlee's (indicating). Those are made by the doctor who talks to the patient.

Q. I just have a few questions here. I would like to use this, Doctor. What do you call this document you were looking at, Doctor?

A. That is the history.

Q. Now, on that history you say that was taken by Dr. Satterlee——

A. Yes.

Q. —— of your office?

A. Yes.

Q. I would like to read into the record, if I may, the portion of it starting down here with [831] "Complaint."

If you want me to read the rest up at the top, I will.

Mr. Neukom: Read any part you want.

Mr. Elson: All right.

Q. Commencing with "Complaint," "Testosterone shots only."

What is that (indicating)?

A. History and physical.

Q. History and physical?

A. Wait a minute. Past history.

Q. What is this?

A. H. P., past history.

Q. Oh, H. P.

A. I guess that is history and present ailment.

Q. H. P. I.?

A. History of past illness.

Q. History of past illness. It reads as follows: Two years ago, this man's testicles and penis began to atrophy and he became sexually impotent. Dr. Openshaw of Salt Lake City has been treating him

(Testimony of Elmer Belt, M.D.)

with a weekly maintenance dose of 50 milligram testosterone Neo-Hombreol. He has been away from Salt Lake City for three weeks. His physician recommended that he come here for the same shots. He will be leaving here for San Francisco shortly. Wants oral prescription for Metandren 10 milligram tablets.

On the reverse side, what is this? [832]

A. Ear, nose and throat.

Q. What is this up here (indicating)?

A. Present illness, "P. I.," it looks like.

Q. And something here. "P. I." the doctor says indicates present illness. The nose, ears, eyes and throat, what is that?

A. Tonsillectomy and adenoidectomy.

Q. Tonsillectomy and adenoidectomy. And then over here, "No venereal diseases, no surgery, general health excellent; two children." What is that (indicating)?

A. "Daughter, age 13—and a boy aged 6 and a girl aged 4."

Q. Boy aged 6 and girl aged 4. What is that (indicating)?

A. "Living and well."

Mr. Elson: Living and well.

Q. (By The Court): Doctor, would that weekly dose you referred to of 50 milligrams be taken all at one time?

A. 50 milligrams would, yes, by hypo, intramuscularly.

Q. Would that be testosterone propionate?

(Testimony of Elmer Belt, M.D.)

A. Propiniate, that would be testosterone propionate in peanut oil.

Q. That was the shots that you gave him?

A. That is right.

Q. Isn't that a rather heavy dose? [833]

A. No. That is not very heavy for a weekly maintenance dose of testosterone.

Mr. Elson: Would your Honor bear with me a minute? I am looking at this.

The Court: Surely.

Mr. Danielson: Did your Honor have any further question on that?

Q. (By The Court): There is just one little item. The witness Parkinson testified that he paid you at your demand \$5 for a treatment. How does that correspond with a similar treatment? For a new patient who would not come from another doctor? [834]

A. If this patient had not been referred to me from another doctor and if this were not a routine thing, a routine procedure, we would have charged him very much more for this entire procedure. Of course, \$5.00 wasn't the total charge here. We explained to him that the laboratory test would be \$6.50, which he said that he would like to have us bill him for to this false address that he gave us. This is a purely courtesy situation here. A patient comes in; he is being treated by another doctor in another city; we do our best to oblige both the doctor and the patient by carrying on the procedure that the doctor feels is indicated. I asked him what Dr.

(Testimony of Elmer Belt, M.D.)

Openshaw charged him for this treatment and he said \$5.00. As a matter of fact, \$5.00 is close to the cost of 50 milligrams of testosterone propionate. I don't know actually what the cost is to our office from the pharmacy but it is not under that. We charged him the same thing that his doctor charged him, as a matter of courtesy to that doctor, and we didn't charge him for the physical examination and for the urine analysis; nothing else except for the laboratory test.

Mr. Elson: I haven't any further questions.

Redirect Examination

By Mr. Danielson:

Q. Just one thing more, Doctor. What is the purpose of the peanut oil in that type of a weekly maintenance shot? [835]

A. It is simply a carrier for the medicine itself, so that it can be conveyed to the patient.

The Court: It makes it last longer in its distribution and effect, doesn't it?

The Witness: Yes; it absorbs slowly from the site.

Mr. Danielson: No further questions.

Mr. Elson: I haven't anything further.

The Court: That is all, Doctor.

Mr. Danielson: Dr. LeTourneau, please.

NORMAN HAROLD LeTOURNEAU, M.D.

a witness for the government in rebuttal, being first duly sworn, testified as follows:

The Clerk: Your full anme?

The Witness: Norman Harold LeTourneau, L-e-T-o-u-r-n-e-a-u.

Direct Examination

Q. (By Mr. Danielson): Dr. LeTourneau, are you an M.D.? A. I am.

Q. A medical doctor? A. Yes, sir.

Q. Where do you practice?

A. At 1893 Wilshire Boulevard.

Q. Are you a member of the Belt Urologic Group? A. That is correct. [836]

Q. Were you so employed on or about June 27, 1949? A. Yes; I was.

Q. Now, Dr. LeTourneau, I direct your attention to a lady sitting here in the front row of the spectators, with a large-brim blue hat on, with red trimming, and ask you if you recognize her.

A. I certainly do.

Q. Did you have any occasion to see her on or about June 27, 1949? A. I did.

Q. And where was that?

A. At 120 Lasky Drive; in the Beverly Hills office of the Elmer Belt Urologic Group.

Q. Doctor, what was the occasion of your seeing her—or do you remember her name?

A. Hannah Shinglman.

(Testimony of Norman Harold LeTourneau, M.D.)

Q. What was the occasion of your seeing Mrs. Shinglman on that day?

A. She came into the office of her own accord, as we thought, as a new patient.

Q. Will you speak louder, please?

A. She came into the office of her own accord and was, as we thought, a new patient, and she was put in a room as a new patient.

Q. Did you have any conversation with her yourself? [837]

A. I did.

Q. What was the substance of that conversation, Doctor?

A. She told me that a Dr. Willard Shinglman, of Cicero, Illinois, was the brother of her husband; that Dr. Shinglman had directed her to our office and that Dr. Shinglman had been giving his brother tablets of, as she phrased it, testosterone linguets.

Q. And by his brother you mean her husband, is that right?

A. That is correct.

Q. Will you continue, please?

A. I made a little note of the conversation, fortunately.

Q. Did you make the notes at that time?

A. At that time.

Q. In the regular course of your business?

A. Yes, sir.

Q. What was this conversation, Doctor?

A. Well, the part that I made a note of, I put down her husband's name as Sigmund Shinglman, who was under the care of Dr. Willard Shinglman, and, in parenthesis, Cicero—I have got Chicago but

(Testimony of Norman Harold LeTourneau, M.D.)
it should have been Illinois. "Dr. Shinglman has his brother on 25 milligrams of testosterone linguets (Metandren). She comes to our office for a [838] refill of the prescription. I advised her that she have Dr. Willard Shinglman write us a letter regarding the patient, explaining his findings and the need for the Metandren, and we would gladly provide a prescription for Metandren linguets." She said she would do this. I gave a prescription for 100 tablets of Metandren linguets.

Q. Doctor, did you make any charge for this prescription?

A. I did not. I did it as a courtesy, or I thought I was doing it as a courtesy to Dr. Willard Shinglman.

Q. As a professional courtesy, is that correct?

A. That is right.

Q. Doctor, did she show you any prescription or any bottle bearing a label at that time?

A. She did not.

Q. Did you see her husband at all?

A. I did not.

Q. Did you request that this husband appear?

A. I told her that she should bring him in for an examination.

Q. Did you say "should" or "would," Doctor?

A. Should.

Q. "S-h"? A. "S-h."

Q. And did she make any reply to that? [839]

A. I don't remember.

(Testimony of Norman Harold LeTourneau, M.D.)

Q. Did she say how long she had been in Los Angeles, Doctor, if you recall?

A. I believe she stated three or four months.

Q. Doctor, was there anyone else present, a nurse or anyone?

A. Not during our conversation. That was in my office.

Mr. Danielson: No further questions, Doctor. Thank you.

Cross-Examination

By Mr. Elson:

Q. Doctor, may I see your note there, please?

I would like to read into the record, if I may, the notes from which the Doctor was reading, that he stated were made, I believe, at the time.

A. That is right.

Mr. Elson: "9250 Olympic Boulevard, Beverly Hills. (No appointment yet.) Mrs. Shinglman re her husband," and then the name under that, "Hannah," and over at the left-hand margin, "June 29, 1949."

"Her husband's name is Sigmund Shinglman, who is under care of Dr. Willard Shinglman, his brother, in Cicero, Chicago. Dr. Shinglman has his brother on 25 milligrams testosterone linguets, Metandren. She comes to our office [840] for refill of prescription. I advised her that she have Dr. Willard Shinglman write us a letter regarding patient, explaining his findings and the need for Metandren and we would gladly provide prescriptions for Me-

(Testimony of Norman Harold LeTourneau, M.D.)
tandren linguets. She stated she would do this. I gave prescription for 100 tablets Metandren linguets.”

Q. Now, Doctor, I show you Defendants’ Exhibit I, which is a prescription on the prescription pad of the Elmer Belt Urologic Group. Is that the prescription that you gave to her at that time?

A. That is correct.

Q. Doctor, isn’t it true that linguets, Metandren linguets, are not manufactured in sizes of 25 milligrams? A. I believe it is.

Q. Metandren is, in fact, a tablet and not a liquid, is it not?

A. It is a trade name. It is called Metandren Linguets, Ciba’s Preparation.

Q. But the name Metandren is the name of the tablets rather than linguets, it is not? [841]

* * *

The Witness: The name of the Ciba preparation is Metandren Linguets.

Q. (By Mr. Elson): Are you sure of that?

A. Yes.

Q. And the linguets come in 25 milligrams?

A. I believe they do.

Q. Are you sure?

A. I am not positive.

Q. What?

A. I have never prescribed it in larger than 10-milligram doses. So I am not positive of that dosage.

Mr. Elson: I have no further questions.

* * *

(Testimony of Norman Harold LeTourneau, M.D.)

Mr Danielson: Your Honor, the government rests.

Mr. Elson: The defense rests. [842]

The Clerk: In what cases?

Mr. Elson: In both cases, United States vs. El-O-Pathic Pharmacy, No. 20,596, Criminal, and United States vs. Allen H. Parkinson, No. 20,642, Criminal [843]

* * *

July 13, 1949, 10:00 o'Clock A.M.

The Clerk: No. 20642, U. S. A. v. Parkinson.

Mr. Elson: Ready.

Mr. Danielson: Ready for the plaintiff.

The Clerk: No. 20596, U. S. A. v. El-O-Pathic and Clemens.

Mr. Danielson: Ready for the Government.

Mr. Elson: Ready for the defendants.

* * *

The Court: As to cases 20596, 20642 and 20608, from the evidence and the weight of the evidence I am convinced, beyond a reasonable doubt, that the indiscriminate distribution or dispensation for use of the drugs Testosterone, Methyl-testosterone, Non-Crystalline Estrone and Alpha Estradiol carries not only a potential but an actual danger of injury to some persons. I am also convinced from the evidence that these drugs do not, other than within a restricted class of cases, produce many or any of the alleviatory and beneficial effects that the labeling given them by the defendants indicate and encourage readers to believe that they will generally produce.

I find, from the evidence and the stipulations between the defendants and the Government plaintiff, that the defendants introduced into interstate commerce misbranded drugs; [3]

Wherefore, I Find the defendant El-O-Pathic Pharmacy, Inc., and Martin A. Clemens Guilty of charges made in the Information in Case No. 20596, in Counts therein, 1 to 14, inclusive; and

I Find the defendant Allen H. Parkinson, trading as Hudson Products Company, Guilty of charges made in the Information in Case No. 20642, in Counts therein, 1 to 4, inclusive.

* * *

Now, it is my construction of those pamphlets, leaflets and circulars enclosed in the packages, by which delivery of sales were made, that they were designed to create a belief that many persons are deficient in their natural testosterone and that by supplementing it with the drug called under various names, a synthetic testosterone, that much benefit could be derived by the user. I do not mean this to convey the impression that I think the defendants intended any fraud. They may, so far as I know, have been acting in full belief of the merits of the drugs for the purposes they recommended them.

I don't think there is anything further that I need say in the cases. [4]

When will the defendants be ready for sentence?

Mr. Elson: So far as the defendants in the El-O-Pathic case and in the Parkinson case are concerned,

they are ready for sentence now, your Honor.

* * *

The Court: You spoke in regard to the Parkinson case, as well as the El-O-Pathic case?

Mr. Elson: Yes, the El-O-Pathic and the Parkinson case.

The Court: That covers all of them, then.

Mr. Elson: Yes, that is correct.

There is only this that I do want to say, in mitigation, your Honor, and that is that your Honor undoubtedly has in mind the fact that in the El-O-Pathic case, Counts 1 to 9, inclusive, were purchases by Government agents, and Counts 3 and 4 in the Parkinson case were likewise purchases by Government agents.

The Court: Very well. Does the Government have anything to say?

Mr. Danielson: If your Honor please, Mr. Roe of the Food and Drug Administration is present in court and we feel [5] that it is possible that your Honor would like to hear from him as to a little of the background of this case, some aspects that did not come out in trial.

The Court: I think not.

Mr. Danielson: Thank you.

* * *

The Court: Martin A. Clemens.

Defendant Martin A. Clemens: Yes, your Honor.

Mr. Danielson: If your Honor please, could I make one additional statement?

The Court: Yes.

Mr. Danielson: In the case of Martin A. Clemens and El-O-Pathic Pharmacy, we feel, your Honor, that because of the magnitude of this operation, the fact that here in yesterday's paper the ads continue, that there should be some substantial penalty imposed.

Mr. Elson: Well now, may I reply to that, please?

The Court: I think I shall reply to that, that so far as I know this is the first time that the defendant [6] Clemens or the El-O-Pathic Pharmacy has been before the court in this matter, and it would follow that the defendant had a right to assume himself innocent until the court passed on it. So that I wouldn't feel disposed to punish him for having carried on the business even though it is now found by the Court to be unlawful.

Mr. Danielson: I understand, your Honor. Thank you.

Mr. Elson: Your Honor has in mind, do you, that Clemens doing business as M. A. Clemens Pharmacy is charged in certain counts, and the El-O-Pathic Pharmacy, of which Clemens is the manager, is the subject of other counts; in other words, they are not included in the same counts?

The Court: That is something that I overlooked.

Mr. Elson: May I call your attention to this, that in Count 1, Clemens as an individual, doing business as Clemens Pharmacy, is the defendant charged; in Count 2 it is the El-O-Pathic Pharmacy or El-O-Pathic Pharmacy, Inc., that is charged, with Clemens of course the manager and director; in

Count 3 it is El-O-Pathic; in Count 4, it is Clemens, doing business as Clemens Pharmacy; so is Count 5; so is Count 6, and so is Count 7; in Count 8 it is El-O-Pathic Pharmacy; in Count 9, it is El-O-Pathic Pharmacy; in Count 10 it is Clemens, doing business as Clemens Pharmacy; in [7] Count 11 it is El-O-Pathic Pharmacy; in Count 12 it is El-O-Pathic; in Count 13 it is Clemens, doing business as Clemens Pharmacy; and in Count 14 it is El-O-Pathic Pharmacy.

Mr. Clemens just acquired the El-O-Pathic about 2 years ago.

The Court: That is 7 counts for Clemens and 7 counts for the El-O-Pathic.

Mr. Elson: I didn't count them.

The Court: I had overlooked that.

I Modify my Finding as to Guilt to conform with that statement of fact; that Mr. Clemens, defendant, is found Guilty in 7 Counts on the Information in case No. 20596.

Mr. Danielson: If your Honor please, I wish in this connection to point out to your Honor that in all of the counts in which the El-O-Pathic Pharmacy is charged, the charge is that El-O-Pathic, incorporated, organized and existing, and so forth, and Martin A. Clemens, an individual, "at the time hereinafter mentioned, the Manager and Director of said corporation," is the Mr. Clemens actually appearing in all counts.

Mr. Elson: That is true, but the reason that I was bringing that to the attention of the court was

so that there would not be any confusion that Clemens [8] Pharmacy and El-O-Pathic were involved in the same counts; in other words, one count will be El-O-Pathic in which Clemens is the director and manager, and there would be another count in which Clemens Pharmacy is the shipper.

Mr. Danielson: That is correct.

The Court: Now, Mr. Danielson, as I understand it now, of these 14 counts, 7 of them are chargeable against Clemens in his individual or in his business relation capacity and 7 are chargeable against the Corporation, El-O-Pathic Pharmacy, Inc.

Mr. Danielson: Well, that is not quite correct, your Honor. In the 7 counts charging the El-O-Pathic, Mr. Clemens as an individual is likewise charged. So, therefore, Mr. Clemens appears as an individual in all 14 counts. The corporation appears only in 7 counts, that is, the El-O-Pathic corporation.

The Court: Well, I am inclined to say that as to the counts involving the corporation, wherein it is found guilty, that Clemens was not acting in an individual capacity, that since the corporation is found guilty on these counts, that they shouldn't lie against an individual. That is my view of it.

Mr. Clemens, the El-O-Pathic Pharmacy, Inc., having been found guilty in 7 counts, It Is the Judgment and [9] Sentence of the Court, this being the first offense, that it pay a fine of One Hundred (\$100.00) Dollars per count, a total of Seven Hundred (\$700.00) Dollars; and you personally, being

found guilty, It Is the Judgment and Sentence of the Court that you pay a fine of (\$100.00) Dollars for each of 7 counts, a total of Seven Hundred (\$700.00) Dollars.

Mr. Elson: Now, your Honor, in connection with that, could we have a stay until Mr. Clemens can get to the bank?

The Court: Yes.

Mr. Danielson: Would your Honor kindly state which counts the fines apply to in each of these cases, in order that the Clerk can make the proper entry?

The Court: Yes, I should like to have counsel——

Mr. Elson: I can assist you on that.

The Court: Yes.

Mr. Elson: As to El-O-Pathic, that would be Count 2, Count 3, Count 8, Count 9, Count 11, Count 12 and Count 14; and as to Clemens, doing business as Clemens Pharmacy, it would be Count 1, Count 4, Count 5, Count 6, Count 7, Count 10 and Count 13.

Mr. Danielson: Thank you.

Then, Mr. Elson, you will stipulate that the Judgment applies to these particular counts named, is that correct, [10] as to each defendant?

Mr. Elson: Yes.

The Court: All right, the Court adopts those recited figures and the Judgments and Sentences so apply.

The Clerk: What about the stay, your Honor?

The Court: The execution of sentence will be stayed. How long do you want?

Mr. Elson: Let us say until tomorrow morning.

The Court: Tomorrow morning, July 14th, 1949, at 10:00 o'clock.

Now, Allen H. Parkinson, you have been found Guilty, on 4 counts. It Is the Judgment and Sentence of the Court that you pay a fine of One Hundred Dollars (\$100.00) on each of the four counts 1, 2, 3 and 4, a total of Four Hundred (\$400.00) Dollars. Are you prepared to pay that at this time?

Mr. Elson: Could we have a stay until tomorrow morning at 10:00 o'clock?

The Court: The same stay, until tomorrow morning at 10:00 o'clock for execution of sentence. [11]

* * *

Certificate

I hereby certify that I am a duly appointed, qualified and acting official court reporter of the United States District Court for the Southern District of California.

I further certify that the foregoing is a true and correct transcript of the proceedings had in the above-entitled cause on the date or dates specified therein, and that said transcript is a true and correct transcription of my stenographic notes.

Dated at Los Angeles, California, this 22nd day of July, A.D., 1949.

/s/ THOMAS B. GOODWILL,
Official Reporter.

[Endorsed]: Filed July 26, 1949.

[Title of District Court and Cause, No. 11,266-HW.]

and

[Title of District Court and Cause, No. 10,391-HW.]

REPORTER'S TRANSCRIPT
OF PROCEEDINGS

Los Angeles, California

Wednesday, March 22, 1950

Appearances:

For the Plaintiff:

ERNEST A. TOLIN, ESQ.,

United States Attorney, by

GEORGE E. DANIELSON, ESQ.,

Assistant United States Attorney.

For the Defendants:

EUGENE M. ELSON, ESQ.,

541 South Spring Street,

Los Angeles 13, California.

The Clerk: United States of America vs. El-Opthic Pharmacy, a corporation, et al., No. 10,266-HW Civil; and United States of America vs. Hudson Products Company, a corporation, et al., No. 10,391-HW Civil.

The Court: Was there any formal stipulation on file relative to this? It was not a consolidation of these two cases, but just a kind of gentleman's agreement?

Mr. Elson: No, that was not stipulated. They were not consolidated, but when we got up to argue them before Judge Cavanah, he asked us if there was anything that was identical between the two cases, and I think I am right, am I not——

Mr. Danielson: That is correct.

Mr. Elson: ——that to a very large extent, there was, but there were certain features of the two cases that were not at all identical, and for that reason I did not want to consolidate them.

So he said, “Well, let’s hear them. Let’s hear what you have to say.”

It was left in rather a nebulous fashion.

Mr. Danielson: It was not too nebulous. Stipulations as to the records were filed on January 31 in each case, and there is listed what should be considered as a part of the record in the case. The cases themselves were not consolidated, but certain items form a part of the record in each case.

The Court: The point at issue is the same in both cases, isn’t it?

Mr. Elson: The point at issue, your Honor—you know how you forget these things when you get away for a few days—the point at issue is whether or not the labeling which is involved in both cases—I think it is the same, isn’t it?

Mr. Danielson: That’s right, the basic point is the same.

Mr. Elson: Whether the labeling is proper.

Mr. Danielson: The law is the same in each case. The facts are slightly different.

Mr. Elson: The facts do vary.

The Court: The only question in these two cases is the question of the labeling?

Mr. Danielson: That is correct.

Mr. Elson: That is right.

The Court: And whether the labeling meets the requirements of the statute or whether it doesn't. I was just wondering if it is going to be necessary to write findings of fact and conclusions of law in both cases. What prompts me is that before, you remember, when I made a ruling denying your preliminary injunction, you came in with a list of findings of fact and conclusions of law.

Mr. Elson: Yes, I did.

The Court: But you came in only on the El-O-Pathic case. I will take it back. You did file, also, on the Hudson case.

Mr. Elson: I was sure I did, because it was a time-consuming thing to do so.

The Court: Well, all right. Then I assume, inasmuch as you have worked so hard on these findings of fact and conclusions of law once before, that it will not be such a problem for the attorneys to prepare the findings, whatever they may.

You know, this case has been with me pretty near ever since I have been on the bench. I think it is one of the first cases that was turned over to me. I have had it on my desk most of the time during the past five months.

I thought I had got rid of it. I was congratulating myself that this was going to be decided by another court and I wouldn't have to decide it, and then through a turn of the wheel, it was sent back

to me and I have been called upon to make a decision.

In a case such as this, it is pretty hard to come to some conclusion, because, usually, there are two sides to the question, and usually there is a difference of opinion. I don't think there is any unanimity of opinion as to the effect of taking these so-called drugs. I think there is medical opinion on both sides. It causes ill effects or it doesn't cause ill effects.

However, it seems to me that it is not a question of what the effect of the taking of the drugs is, but the main issue is what is on the packages, how it is described, what is said.

As counsel has pointed out, after the criminal hearing he attempted to sit down and comply with the ruling in that case. Well, the plaintiff in this case is in the position of lawyers many times when some defendant gets into trouble and comes into the office, and you say, "You shouldn't have done that." It is very easy to tell people what they shouldn't have done. It is a great deal more difficult to tell people what they should do.

I am quite sure that it has been the experience of most attorneys that when people come into your office, you say, "Well, you shouldn't have done that." After the thing is done and it doesn't turn out in the proper way, you always are in a position to say, "That was the wrong thing to do. It didn't have the proper results."

Since this matter has been submitted to me the second time, I have gone over the pleadings and I

have read your complaint and I have read your answer. I have read the argument made before Judge Cavanah, that is, according to the transcript. I have read your affidavits, too. I have come to a conclusion.

I notice—I believe it is one of the arguments of the defendants in this case—that the plaintiff says, “You can’t do it this way.” They never tell them how they can do it.

According to the affidavits of Mr. Elson, when he talked to someone whom he has identified as a doctor of medicine employed by the Food and Drug Administration in Washington, he asked the question whether or not any kind of a description would have been sufficient and he, purportedly, got the reply that it was the purpose to see that these products were only sold on prescription. So I am rather doubtful whether or not the defendant in this case could write any sort of matter upon a small box, upon a small container, which would meet all of the objections of the Food and Drug Administration.

It is claimed, on more than one occasion during the proceedings, that sufficient warnings were not given. Yet I have gone through the pleadings for the last time this morning, and I notice in both cases that physicians are mentioned four times.

In your original complaint, you set out the descriptive matters upon the cartons. There is no dispute as to what was printed on the cartons. The cartons are before the court. They can be read.

In all cases, on both of these cases, as far as I am

able to ascertain, the word "physician" is used at least four times, "under supervision of a physician," "under direct supervision of a physician," and I don't know what more words would be put upon their cartons that would be a greater warning, except, "to be used only upon a prescription from a physician."

I think that is what the Food and Drug people are trying to get at. That is, they want these medicines to be sold only upon the prescription of a physician.

There has been considerable testimony here about the effects that would follow if the substances are taken by persons under certain physical conditions. Again, that is a disputed fact. The doctors don't agree.

I have not been able to make up my mind that the plaintiff is entitled to the relief he has asked for in these complaints. I think the burden of proof is upon the plaintiff. At least, as far as I am concerned, the plaintiff has not sustained the burden of proof.

Consequently, I think a judgment will be entered in favor of the defendants and against the plaintiff.

Certificate

I hereby certify that I am a duly appointed, qualified and acting official court reporter of the United States District Court for the Southern District of California.

I further certify that the foregoing is a true and correct transcript of the proceedings had in the

above-entitled cause on the date or dates specified therein, and that said transcript is a true and correct transcription of my stenographic notes.

Dated at Los Angeles, California, this 27th day of March, A.D. 1950.

/s/ S. J. TRAINOR,
Official Reporter.

[Endorsed]: Filed August 2, 1950.

[Title of District Court and Cause, No. 20,596-Criminal.]

STIPULATION OF FACTS

The parties, through their respective counsel, agree that the only significant issue to be decided is whether the drugs involved were misbranded or were not misbranded; and so as to conserve time and to avoid testimony with respect to undisputed facts, and in order that the real issue may be promptly placed before the Court, they do agree specifically as follows:

1. Defendant Martin A. Clemens is the manager and director of defendant El-O-Pathic Pharmacy, Inc., a corporation, and also trades and does business under the firm name of M. A. Clemens Pharmacy, both businesses being located at Los Angeles, California; at all times referred to in the criminal information filed in this case, said defendant Clemens was the manager and director of said El-O-

Pathic Pharmacy, Inc., and also traded and did business under the firm name of said M. A. Clemens Pharmacy.

2. With respect to the alleged interstate and intrastate shipments and sales by the defendants of the drugs with their accompanying labeling as described in the fourteen counts of the criminal information, it is agreed that said defendants caused such shipments and sales on the dates and in the manner specified in each count.

3. With respect to the alleged interstate and intrastate shipments and sales by persons other than the defendants of the drugs described in Counts 4 through 9, inclusive, it is agreed that such shipments and sales transpired on the dates and in the manner specified in those counts.

4. The composition of each drug is as declared on the labeling of said drug, which labeling is hereinafter identified in this Stipulation and appended as exhibits; the composition of the drug involved in Count 10 (which is not declared in the labeling) is 0.5 mg. alpha-estradiol per tablet. The drug involved in Count 10 was shipped in package form.

5. Said defendants did not require or receive a physician's prescription in the shipment or sale of any of the drugs involved in Counts 1 through 14, inclusive.

6. Appended to this original Stipulation and incorporated herein are Government Exhibits 1, 1(a) etcetera through 14(a), inclusive. Said ex-

hibits have been so numbered subject to the Court's approval. Each exhibit has been given a number to be readily identified with the count to which it is relevant. In instances where there are more than one item, the second, has been marked Exhibit 1(a), 6(b), etcetera.

Government's Exhibit 1 bears the labeling referred to in Count 1; Government's Exhibit 2 bears the labeling referred to in Count 2, and to like effect with respect to Government Exhibits 3 through 14(a), inclusive, as specifically identified in each of the attached exhibits. Each item comprising this labeling is as identified in each exhibit. Each such item appears exactly as it was when received by the consignee designated in each exhibit, with the sole exception that the Food and Drug inspectors who collected these items wrote official sample numbers, dates of collection, and their initials upon each item.

The original exhibits referred to in each of the counts are attached to the original of this stipulation. The copies of this stipulation contain photostats thereof, however, so far as a certain circular or pamphlet is concerned, the copies reflect but a portion of said circular. The parties are familiar with said circular and are content to so identify it in the copies of this Stipulation without requiring it to be fully photostated. This circular is a four page printed pamphlet bearing on the front thereof, among other writings, "Male and Female Sex Hormones."

7. Each of the drugs involved in Counts 1 through 14, inclusive, was manufactured by an out-of-state manufacturer; during the interstate and intrastate journeys of said drugs from the manufacturers to the defendants, the labeling of each such drug bore the legend: "Caution: To be dispensed only by or on the prescription of a physician." In the transactions described in Counts 1, 2, 4, 5, 6, 7, 8, 9, 10, 11, and 13, defendants repackaged the drugs as received from the manufacturers before making the shipments and sales involved in those counts. In the transactions described in Counts 3, 12, and 14, defendants shipped and sold the drugs in the original packages as received from the manufacturers. In no instance did the defendants alter the composition of any of said drugs. The circular "Male and Female Sex Hormones" did not accompany any of said drugs in their interstate or intrastate movement from the manufacturers to the defendants.

Dated: June 15th, 1949.

JAMES M. CARTER,
United States Attorney.

NORMAN W. NEUKOM,
Assistant U. S. Attorney,
Chief, Criminal Division.

/s/ GEORGE E. DANIELSON,
Assistant United States Attorney, Attorneys for
United States of America.

/s/ CARL B. STRUZENACKER,
Attorney for Defendant.

Count One

GOVERNMENT'S EXHIBIT 1
(20596)

Label on a product, as received by John R. Winch,
of Phoenix, Arizona.

Male Hormone

Each tablet contains 25 mg. testosterone the form of the true male sex hormones which is most highly effective for administration by mouth. The availability of methyl testosterone makes possible the convenience of oral administration in applying androgenic therapy. The oral dose of methyl testosterone is about 1-2 tablets daily.

Trial Size	\$ 2.00
Box 30 Tablets	10.00
Box 60 Tablets	19.00
Box 100 Tablets Professional Size..	29.95

Send Mail Order to M. A. Clemens (Pharmacist)
426 So. Spring St., Room 502-503
Los Angeles 13, Calif.
MAdison 6-4171

[In Longhand]: 30-046 K 11-1-47.
JRW.

Admitted June 22, 1949.

GOVERNMENT'S EXHIBIT 1(a)
(20596)

Circular that accompanied drug, as received by
John R. Winch of Phoenix, Arizona.

[In Longhand]: 30-046 K 11-1-47.

JRW.

Male and Female Sex Hormones
M. A. Clemens
(Pharmacist)

Distributors of Vitamins and Hormones
Sanitary Rubber Goods

Endocrine preparations of unusual quality for
Male and Female

426 South Spring Street Rooms 502-503
Los Angeles 13, Calif.

MA. 64171

MA. 64172

Male Hormone

Testosterone

This discovery of the Male Sex Hormone is one of the achievements of modern medicine on which the public is comparatively uninformed. Yet it is truly a tremendous accomplishment.

Prof. Ruzicker, a Swiss chemist, succeeded in making Testosterone, "the most potent male hormone" by synthetic means; and for this he received The 1939 Nobel Prize in Chemistry.

"Science is unlocking the secrets of Male and Female sex hormones. Years of scientific effort and research have established that these hormones accomplish many things which up to a few years ago

were thought to be impossible. These discoveries are far-reaching and assisting millions of men and women to lead happier lives, and are relieving and postponing the many conditions associated with middle age."

The Sex Hormones

All hormones play a major part in the sexual makeup of the hormonal system. The male hormone stimulates growth and development of the sex organs and of the male sex characteristics, such as distribution of hair, muscular development, depth of voice and the improvement of a sense of well-being.

Male Hormone Deficiency

The average man in his late forties begins to enter what is called the "climacteric" period at which time the body undergoes a radical change. Although most of these changes may start during middle age, they may also show up at almost any time during middle age. As a rule there may be flushes, sweats and chills. Lack of sexual power, impaired memory, irritability, inability to concentrate on activities or a tendency to evade them, nervousness, depression, general weakness and poor physical strength are some of the major signs which are associated with this declining period.

Impotence

Lack of sexual desire and inability to perform the sexual act is one of the most common complaints of the male "climacteric." When due to a deficiency of the male sex hormone, these conditions

usually respond promptly to male hormone therapy, which assist in restoring sexual desire and ability to fulfill it. In addition to re-establishing potency, the male sex hormone helps to relieve other conditions which frequently occur during this period.

Results From Male Hormone

These social, sexual, physical and mental conditions may be overcome by the use of the male sex hormones, which often bring about startling changes. At first, it may be noticed there is a marked improvement in physical and mental work and a tonic action resulting in renewed vigor. A better attitude towards business and social life is frequently observed. Nervousness, exhaustion and melancholy gradually disappear and in the large majority of instances the improvement persists over a long period of time.

Just One Tablet a Day and Eliminate Unnecessary Injections New 25 mg Tablet

30 Tablets	\$10.00
100 Tablets	29.95
200 Tablets	57.50

No Prescription Required
Add 3% Sales Tax for Mail Orders

Prices on Testosterone for Injection by Request

Male Hormone

Linguets . . . under the tongue
when Oroal Male Hormone Therapy is Indicated
are effective in doses $\frac{1}{2}$ to $\frac{2}{3}$ the amount required
when methyl testosterone is ingested. Greater economy, convenience and ease of administration mark Metandren Linguets as one of the great advances in androgenic therapy.

The Most Economical Oral Androgen

The sublingual administration of methyl testosterone in the form of Linguets is based on direct venous drainage from the oral mucous membranes. The androgen is carried in the blood by the systemic venous system to the right heart, thence through the pulmonary circulation back to the left heart and thus is first distributed by the general circulation to all organs and tissues. By this route methyl testosterone by-passes the liver and escapes partial inactivation. Consequently, complete dosage is delivered to the tissues more rapidly and without loss.

Regular Strength

Box 50 Tablets Linguets. . \$ 7.00 plus 3% sales tax
Box 100 Tablets Linguets. . 13.00 plus 3% sales tax
Box 200 Tablets Linguets. . 25.00 plus 3% sales tax
Box 500 Tablets Linguets. . 60.00 plus 3% sales tax

Double Strength

Box 100 Tablets Linguets. . \$17.00 plus 3% sales tax

No Prescription Required

Many excellent Reports for the Non Professional layman have already appeared in the following publications:

Readers Digest by Paul de Kruif, July, 1944
—August, 1946.

Newsweek, March, 1943.

Time, May 28, 1945.

Newsweek, May 28, 1945.

Liberty, February 2, 1946.

*Paul de Kruif's sensational book, "The Male Hormone," Harcourt-Brace.

Information and Prices on Ampules or Vials
Sent by Request

Female Hormone

A-Estradiol

The estrogenic hormone promotes the development of sex characteristics in the female.

It maintains the normal condition of these characteristics in the normal adult woman.

a-Estradiol preparations confer a definite "sense of well-being."

a-Estradiol offers clinically important advantages.

a-Estradiol is the genuine hormone of the ovarian follicle, which is "probably the most potent of all known estrogens."

a-Estradiol has a smooth, dependable action which speedily controls the symptoms of ovarian

*Send \$1.00 plus 15c for mailing.

deficiency and produces a gratifying sense of well-being. a-Estradiol is not likely to provoke side reactions or after-effects, such as headache, dizziness and gastrointestinal disturbances, which frequently complicate the action of artificial estrogens. Because of their high potency, oral a-estradiol tablets may be used in place of parenteral therapy in most cases. The elimination of frequent injections means not only more comfort and convenience for the patient—it also saves the physician both time and energy.

The especial therapeutic value of a-estradiol preparations, particularly as compared with estrone (theelin) and estriol (theelol), is today widely appreciated, since the latter now appear to be secondary products of minor importance.

The Change of Life

Although this period which occurs between the fourth and fifth decades of life may pass with hardly any complaints, in many women it may cause disorders which may interfere seriously with normal living. These disorders may be mild or severe, depending upon the individual. Headache, insomnia and dizziness are frequently complained of. In severe cases, there may be fear, crying spells sometimes accompanied by melancholy and emotional instability.

Prices—A-Estradiol Tablets

30 Days Supply	\$10.00
60 Days Supply	17.50

Breast Development

Direct Action on the Mammary Gland

Estrogens can be absorbed through the skin of the human female directly into the breast tissue and by this route can produce their characteristic stimulation of mammary growth and the result is "definite breast growth of considerable degree." Since underdeveloped breasts are often a considerable worry to women, cutaneous estrogen therapy of hypomastia presents a valuable addition to the physician's therapeutic resources.

25 Days Supply (50,000 International

Units)\$ 7.50

25 Days Supply (125,000 International

Units) 14.00

No Prescription Required

Government's Exhibit 3(a). Photostat of above label taken before label was slightly torn in being removed from box.

GOVERNMENT'S EXHIBIT 3(a) (20596)

30-068K 125-047-00

MENFORMON DOSULES

'ROCHE-ORGANON'

(FEMALE SEX HORMONE PREPARATION IN INDIVIDUAL DOSE CONTAINERS FOR ACCURACY OF DOSAGE)

Each bottle contains 12 tablets. The tablets are white and round. They are marked with the letters "R" and "M". The tablets are to be taken orally, with or without food, at the same time each day. The tablets are to be taken for 12 days, starting on the first day of the menstrual period. The tablets are to be taken for 12 days, starting on the first day of the menstrual period. The tablets are to be taken for 12 days, starting on the first day of the menstrual period.

FOR EXTERNAL USE ONLY

ROCHE-ORGANON Inc., NUTLEY, NEW JERSEY

FOR APPLICATION

1. Remove the cap from the bottle.

2. Dip the applicator into the bottle.

3. Apply the cream to the skin.

4. Rub the cream into the skin.

5. Wash the applicator with soap and water.

6. Store the applicator in the bottle.

CAUTION: To be applied only to the skin. Do not use on the face. Do not use on the neck. Do not use on the chest. Do not use on the arms. Do not use on the legs. Do not use on the hands. Do not use on the feet. Do not use on the scalp. Do not use on the hair. Do not use on the nails. Do not use on the teeth. Do not use on the mouth. Do not use on the throat. Do not use on the larynx. Do not use on the trachea. Do not use on the bronchi. Do not use on the lungs. Do not use on the heart. Do not use on the stomach. Do not use on the intestines. Do not use on the bladder. Do not use on the uterus. Do not use on the vagina. Do not use on the cervix. Do not use on the ovaries. Do not use on the fallopian tubes. Do not use on the uterus. Do not use on the vagina. Do not use on the cervix. Do not use on the ovaries. Do not use on the fallopian tubes.

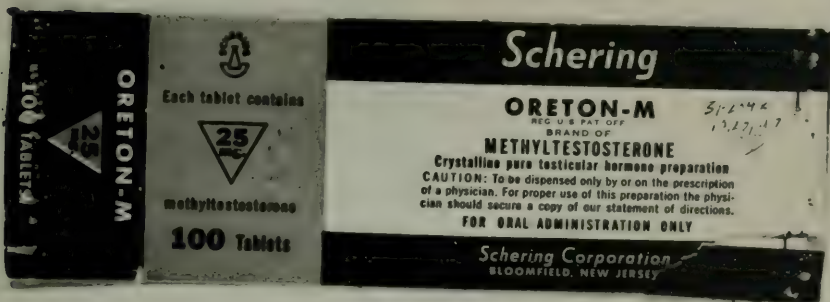
KEEP IN A COOL PLACE

Count Six

Government's Exhibit 6. Label on carton of drug, as received by Forum Drug Co., and by M. A. Clemens Pharmacy, both at Los Angeles, California.

Front View

GOVERNMENT'S EXHIBIT No. 6 (2596)



Admitted June 22, 1949.

Government's Exhibit 6(a). Label on envelope of drug, as received by Alan T. Spiner.

GOVERNMENT'S EXHIBIT 6(a) (2596)

MALE HORMONE

Each tablet contains 25 mg. testosterone the form of the true male sex hormone which is most highly effective for administration by mouth. The availability of methyl testosterone makes possible the convenience of oral administration in applying androgenic therapy. The oral dose of methyl testosterone is about 1-2 tablets daily.

Trial Size	\$ 2.00	51-242
Box 30 Tablets	10.00	13,271-17
Box 60 Tablets	19.00	DB.
Box 100 Tablets Professional Size	29.95	

Send Mail Orders to M. A. CLEMENS (Pharmacist)
 428 So. Spring St., Room 502-500 Los Angeles 13, Calif. MADISON 6-4111

Admitted June 22, 1949.

COUNT EIGHT

Government's Exhibit 8. Label on bottle of drug, as received by El-O-Pathic Pharmacy at Los Angeles, California.



Government's Exhibit 8(a). Label on envelope of drug, as received by Alan T. Spiher.

NOTE: Please understand this size is simply an introductory package and for maximum results treatment must be continued over a 30-day period.

31-208K
11/20/47
ATP
Exhibit C

MALE HORMONE

Each tablet contains 25 mg. testosterone the form of the true male sex hormone which is most highly effective for administration by mouth. The availability of methyl testosterone makes possible the convenience of oral administration in applying endrogenic therapy. The oral dose of methyl testosterone is about 1-2 tablets daily.

Trial Size	\$ 2.00
Box 30 Tablets	10.00
Box 60 Tablets	19.00
Box 100 Tablets Professional Size	29.95

31-208K
11/20/47
ATP
Exhibit C

Send Mail Orders to EL-O-PATHIC PHARMACY
1108 1/2 No. Western Ave. Hollywood 27, Calif.

HOLLYWOOD 1723

Count Thirteen

Government's Exhibit 13, label on bottle of drug,
as received by D. J. McBride, at Tucson, Arizona.

GOVERNMENT'S EXHIBIT No. 13
(20596)

Male Hormone

Each tablet contains 5 mg. testosterone the form
of the true male sex hormone which is most highly
effective for administration by mouth. The avail-
ability of methyl testosterone makes possible the
convenience of oral administration in applying
androgenic therapy.

The oral dose of methyl testosterone is 2 tablets
3 times daily. Place 2 tablets under the tongue and
allow them to dissolve.

Box 50 Tablets Linquets\$ 7.00

Box 100 Tablets Linquets 13.00

Send Mail Orders to

M. A. CLEMENS (Pharmacist)

426 So. Spring St., Room 502-503,

Los Angeles, 13, Calif.

Successor to Clark's Drugs & Sundries

Admitted June 22, 1949.

[Longhand]: 31-220 K 1/30/48.

AB.

[Endorsed]: Filed June 22, 1949.

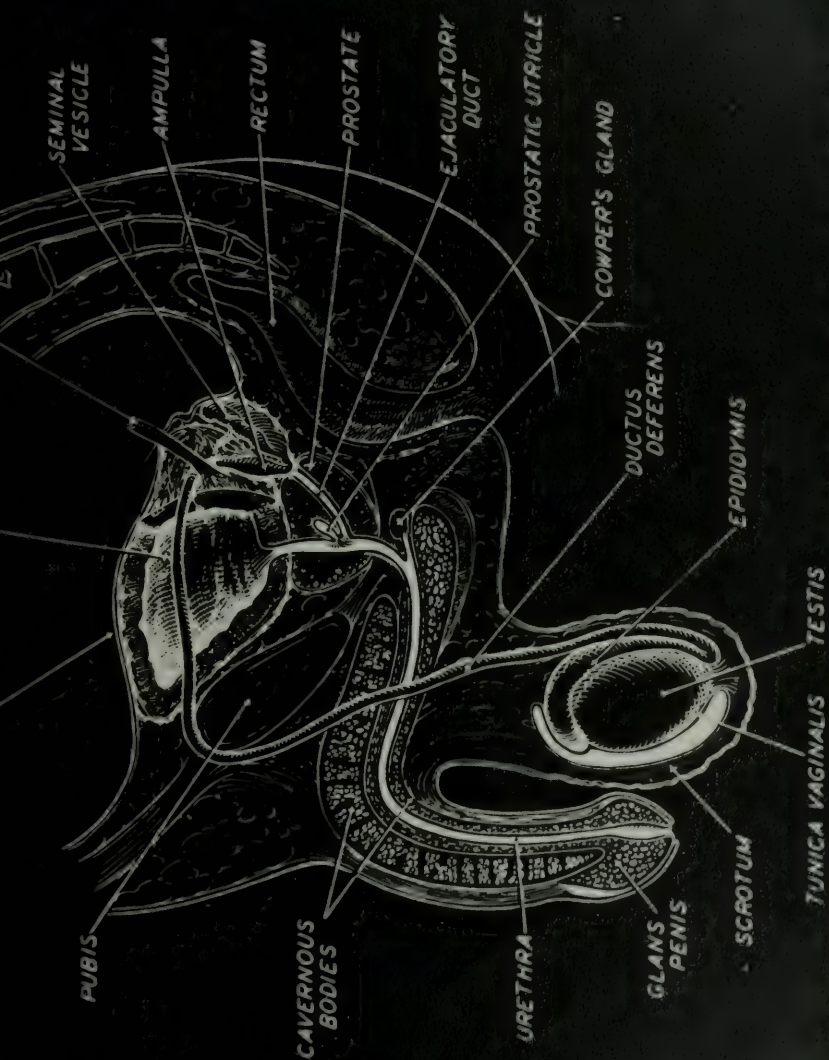


Fig. 51. A diagrammatic sagittal section of the male pelvis, showing the genital organs and their relations to the bladder and urethra.

GOVERNMENT'S EXHIBIT No. 18
(20596)

Hormone Preparations

Memo to Chief

3/25/48

AB.

Roche-Organon Inc.

Nutley 10, New Jersey

Hormones

July 1947

Gentlemen:

One of our most popular dealer helps is our literature imprinting service. Demands for Roche-Organon literature bearing the name and address of the individual dealer have increased by leaps and bounds. Because of the growing popularity of this service and because a number of dealers have only recently become Roche-Organon distributors, we should like to repeat and reemphasize the salient points of this service.

As you know, it is the firm policy of Roche-Organon never to advertise its products to the laity; therefore, the literature which you request and receive is for distribution only to your physicians. In fact, all of the more recent Roche-Organon literature bears this legend: "This pamphlet has been prepared for dissemination to the medical profession exclusively."

All Roche-Organon products, with the exception of Cytora, are strictly prescription items; literature, therefore, must be kept out of the hands of your

customers. You would be breaking faith with your physicians to do otherwise. In fact, you might even endanger lives, for hormones are powerful therapeutic agents which must be administered under strict medical supervision.

So pass along these facts to all your clerks: (1) Roche-Organon literature is for physicians only. (2) Keep Roche-Organon literature out of reach of your customers. (3) All Roche-Organon products (except Cytora) bear an Rx legend on their labels, and therefore may be dispensed only on a physician's prescription. (4) Don't give out literature with prescriptions for Roche-Organon products even when the patient asks for it.

Strict observance of these rules means that the professional standing of your store will rise. Your physicians will regard your store as a truly professional hormone headquarters.

Sincerely yours,

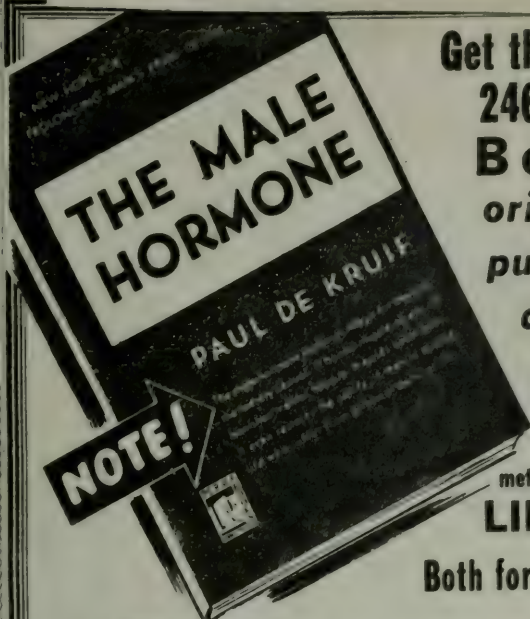
/s/ ROCHE-ORGANON, INC.

NAL:GF

Admitted July 5, 1949.

(Advertisement taken from the Los Angeles Times--Page 32 Part 1, April 17, 1949.)

were
cerem



Get this Great
246-page
Book
originally
published
at \$2.50
with
50
methyl testosterone
LINGUETS

Both for \$5¹⁵
including
tax

OVER 40? Nervous? Depressed?

Easily tired? Forgetful—confused—think you are no longer “good for much”? If you have felt any or all of these discouraging symptoms, you should read this splendid, hope-inspiring volume. Then try magic methyl testosterone, that Dr. Albert Hemming, noted authority, states “can go far toward revitalizing a man who is going through a male ‘change of life.’”

This is **your opportunity** to prove it for yourself. Here is a large enough quantity for a real test, at the lowest cost yet offered—and in a form **TWICE AS EFFECTIVE** as tablets you swallow—LINGUETS that **melt** under your tongue and are absorbed **directly** into the system.

Don't put off the new life, energy, happiness that may be yours! Send cash, check, money order (or order C.O.D.) with the coupon **TODAY!** Or come in and see our REGISTERED PHARMACIST.

Other **guaranteed** hormone products for women—

FEMALE HORMONES
MONTH'S SUPPLY—SPECIAL
BREAST DEVELOPMENT
25 APPLICATIONS OF HORMONES

\$5¹⁵
incl tax
\$7⁷³
incl tax

FREE LITERATURE!

FREE PARKING!

PHONE HO 9-1722

ELOPATHIC PHARMACY, Dept. T-4,
1109½ No. Western Ave., Hollywood 27, Calif.

☐ ENCLOSED FIND \$5 15 FOR 50 LINGUETS AND THE MALE HORMONE BOOK
☐ \$5 15 FOR FEMALE HORMONE (tax incl.) ☐ \$7 73 for BREAST DEVELOPMENT

NAME

ADDRESS

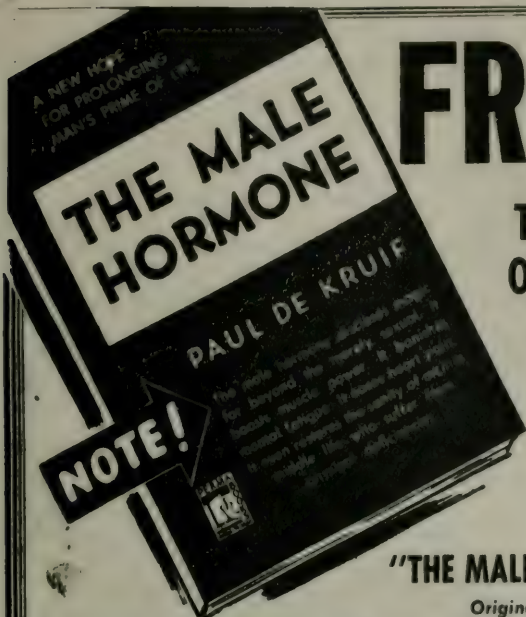
CITY & STATE

Admitted July 6, 1949.

(Advertisement taken from the Los Angeles Times--Page 22, Part 1, June 8, 1949.)

Angeles

of this



FREE!

TO MEN OVER 40

**SPECIAL OFFER
LIMITED TIME!**

Paul De Kruif's
great book

"THE MALE HORMONE"

Originally \$2.50

WITH PURCHASE OF 50 LINGUETS

Regularly \$7.50

BOTH

NOW ONLY

\$5.00

Plus 15c
Sales Tax

NERVOUS? TIRED? DEPRESSED?

Now Try Double Effective

MALE HORMONES

Don't put off new life—renewed energy and happiness that may be yours! A 30 to 50-day trial will prove how much more vigorous—alert—alive you may feel! How much more vital in your home and business life! Try magic methyl testosterone, that Dr. Albert Hemming, noted authority, states "can go far toward revitalizing a man who is going through a male 'change of life'." Methyl testosterone linguets melt under the tongue . . . get into the system directly . . . **DOUBLE** the effect of tablets you swallow!

FEMALE HORMONES Breast Development

FREE LITERATURE

MONTH'S SUPPLY, SPECIAL
25 APPLICATIONS OF HORMONES

FREE PARKING
REGISTERED PHARMACISTS

\$5.00 add 15c tax

\$7.50 add 23c tax

PHONE NO. 9-1722

HEOPATHIC PHARMACY, Dept. 2-4,
1109 1/2 No. Western Ave., Hollywood 27, Calif.

☐ ENCLOSED FIND \$3.15 FOR 30 LINGUETS AND "THE MALE HORMONE" BOOK.
☐ \$5.15 FOR FEMALE HORMONE (tax incl.) ☐ \$7.75 FOR BREAST DEVELOPMENT.

NAME _____

ADDRESS _____

CITY & STATE _____

Admitted July 6, 1949.

GOVERNMENT'S EXHIBIT No. 24
(20596)

(Advertisement taken from the Los Angeles Daily News, Page 8-B, July 5, 1949.)

Over 40?
Now—Try

Doubly Effective
Male Hormones

Find out how much more vigorous, alert, alive you may feel—how much more vital in your home and business life!

For a real test, you need 30 to 50 days. So for a short time, we make this unprecedented

Special Offer!
50 Linguets, \$5.00
add 15c sales tax

Lowest price ever for the most effective way to take methyl testosterone, the genuine Male Hormone! They melt under the tongue—get into the system directly—Double the effect of tablets you swallow! Send cash, check, money order (or order C.O.D.) Now! Other guaranteed hormone products also mailed first class, in plain wrapper.

Female Hormones
Month's Supply—Special—\$5.00
add 15c sales tax
Breast Development
25 applications, \$7.50
add 23c sales tax

Don't delay—send in
your order Now!

Elopathic Pharmacy
Dept. T-5
1109½ N. Western Ave.
near Santa Monica Blvd.
Los Angeles 27, Calif.

Registered pharmacist in attendance

Free Parking!

Free Literature!

Admitted July 6, 1949.

DEFENDANT'S EXHIBIT B
(20596)

Report of Dangerous Drug Committee, State Board
of Pharmacy, March 24, 1948

Report based on information obtained through
four public hearings and 16 responses to question-
naire from experts.

1. Two hearings held on Estrogenic substances,
one in Los Angeles and one in San Francisco.

2. Two hearings held on Estrogenic and Andro-
genic Sterols, one in Los Angeles and one in San
Francisco.

3. 16 questionnaires returned from Medical ex-
perts.

Of the 16 questionnaires returned on the question
of the Carcinogenic properties of Estrogenic sub-
stances there were eleven Noes and 5 Yeses.

On the question of Dangerous Properties and
question of restriction, there were 16 Yeses to both

questions but very little supporting evidence to show why they were dangerous.

The public hearings were not well attended, which signifies that there is little public interest in the matter. Most of those present were of the opinion that Estrogenic Substances should be restricted, but no evidence was brought out as to why this should be done and no specific case of injury to anyone was cited. There were some vague references to "bleeding" being produced in some patients.

On the question of Androgenic Substances, no evidence was presented to indicate that they were harmful and no specific case of injury was cited. The preponderance of evidence seemed to be that they are not harmful or dangerous, except that they might "light up" an incipient cancer of the prostate.

Conclusion of the Committee

In the absence of any specific cases of harmful effect attributable to the substances considered and due to lack of interest and any demand on the part of the public, the committee feels that no action should be taken by the Board at this time. But that we should await the results of the study now being undertaken by the Federal Government.

The committee further recommends that it be kept standing and continue its study of the problem. And that it endeavor to obtain information relative to the volume and extent of use of estrogenic substances for self medication.

/s/ A. J. AFFLECK,
Chairman.

Admitted July 6, 1949.

[Title of District Court and Cause. No. 20642—
Criminal.]

STIPULATION OF FACTS

The parties, through their respective counsel, agree that the only significant issue to be decided is whether the drugs involved were misbranded or were not misbranded; and so as to conserve time and to avoid testimony with respect to undisputed facts, and in order that the real issue may be promptly placed before the Court, they do agree specifically as follows:

(1) Defendant Allen H. Parkinson is an individual trading and doing business under the firm name of Hudson Products Company at Long Beach, California: at all times referred to in the criminal information filed in this case, said defendant Parkinson was trading and doing business under said firm name of Hudson Products Company at Long Beach, California.

(2) With respect to the defendant's alleged interstate shipments and sales of the drugs with their accompanying labeling as described in the four counts of the criminal information, it is agreed that said defendant caused such shipments and sales on the dates and in the manner specified in each count.

(3) The composition of each drug is as declared on the labeling of said drug, which labeling is hereinafter identified in this Stipulation and appended as exhibits.

(4) Said defendant did not require or receive a physician's prescription in the shipment or sale of any of the drugs involved in Counts 1-4, inclusive.

(5) Appended to this original Stipulation and incorporated herein are Government's Exhibits 1, 1(a), et cetera, through 4(b), inclusive. Said exhibits have been so numbered subject to the Court's approval. Each exhibit has been given a number to be readily identified with the count to which it is relevant. In instances where there are more than one item, the succeeding items have been marked Exhibit 1(a), 4(b), et cetera.

Government's Exhibit 1 bears the labeling referred to in Count 1; Government's Exhibit 2 bears the labeling referred to in Count 2, and to like effect with respect to Government's Exhibits 3 and 4, as specifically identified in each of the attached exhibits. Each item comprising this labeling is as identified in each exhibit. Each such item appears exactly as it was when received by the consignee designated in each exhibit, with the sole exception that the Food and Drug inspectors who collected these items wrote official sample numbers, dates of collection, and their initials upon each item.

The original exhibits (in some instances, photostats thereof) referred to in each of the counts are attached to the original of this stipulation. The copies of this stipulation contain photostats thereof; with respect to the leaflets comprising some of the exhibits, the copies reflect but a portion of such leaflets. The parties are familiar with said leaflets

and are content to identify them in this manner in the copies of this stipulation without requiring them to be fully photostated. These leaflets are respectively entitled "The Male Hormone" and "The Story of Hormones."

(6) Each of the drugs involved in this case was manufactured by an out-of-state manufacturer; during the interstate and intrastate journeys of said drugs from the manufacturers to the defendant, the labeling of each such drug bore the legend: "Caution: To be dispensed only by or on prescription of a physician." Defendant repackaged the drugs as received from the manufacturers before making the shipments and sales involved in this case. In no instance did the defendant alter the composition of any of said drugs. Neither the leaflet entitled "The Male Hormone," nor the leaflet entitled "The Story of Hormones" accompanied any of said drugs in their interstate or intrastate movement from the manufacturers to the defendant.

(7) It is expressly agreed that the Court may consider the evidence produced in this Court in the case of *United States v. El-O-Pathic Pharmacy, Inc., et al.*, No. 20,596—Criminal, to be a part of the record in the instant case, insofar as such evidence is pertinent here, the same as if such evidence had been given in the trial of the instant case, subject to the same objections as were originally raised in the presentation of such evidence. It is further expressly agreed that both parties reserve the right to

offer any additional evidence that is relevant, competent, and material.

Dated: July 7th, 1949.

JAMES M. CARTER,
United States Attorney.

NORMAN W. NEUKOM,
Assistant United States
Attorney, Chief, Criminal
Division.

/s/ GEORGE E. DANIELSON,
Assistant United States Attorney, Attorneys for
United States of America.

/s/ EUGENE M. ELSON,
Attorney for Defendant.

Count One

Government's Exhibit 1. Label on carton of drug as received by Roy H. Downing of Altoona, Pennsylvania.

GOVERNMENT'S EXHIBIT No. 1 (20642)

Male Sex Hormones

(30) 10 Mg. Methyl-Testosterone Tablets

Dosage: 1 Tablet Daily

Important—In case of pronounced male sex hormone deficiency take 3 tablets daily for 10 days.

After the 10 day period take 1 tablet daily.

Caution: Take Only as Directed.

Hudson Products Co.

341 Harding Street, Long Beach 5, Calif.

[Stamped]: 6-134 K Jul. 16, 1948.

[Initialed]: D.F.F.

Government's Exhibit 1(a). Leaflet "The Male Hormone" that accompanied drug, as received by Roy H. Downing of Altoona, Pennsylvania.

GOVERNMENT'S EXHIBIT No. 1(a)
(20642)

The Male Hormone
Methyl-Testosterone
The True Male Sex Hormone



This discovery of the Male Sex Hormone is one of the achievements of modern medicine on which the public is comparatively uninformed. Yet it is truly a tremendous accomplishment.

Prof. Ruzicker, a Swiss chemist, succeeded in making Testosterone, "the most potent male hormone" by synthetic means; and for this he received The 1939 Nobel Prize in Chemistry.

"Science is unlocking the secrets of Male and Female sex hormones. Years of scientific effort and research have established that these hormones accomplish many things which up to a few years ago were thought to be impossible. These discoveries are

far-reaching and assisting millions of men and women to lead happier lives, and are relieving and postponing the many conditions associated with middle age."

The Sex Hormones

All hormones play a major part in the sexual makeup of the hormonal system. The male hormone stimulates growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development, depth of voice and the improvement of a sense of well-being.

Male Hormone Deficiency

The average man in his late forties begins to enter what is called the "climacteric" period at which time the body undergoes a radical change. Although most of these changes may start during middle age, they may also show up at almost any time during middle age. As a rule there may be flushes, sweats and chills. Lack of sexual power, impaired memory, irritability, inability to concentrate on activities or a tendency to evade them, nervousness, depression, general weakness and poor physical strength are some of the major signs which are associated with this declining period.

Impotence

Lack of sexual desire and inability to perform the sexual act is one of the most common complaints of the male "climacteric." When due to deficiency of the male sex hormone, these conditions usually respond promptly to male hormone therapy, which as-

sist in restoring sexual desire and ability to fulfill it. In addition to re-establishing potency, the male sex hormone helps to relieve other conditions which frequently occur during this period. [385]

Results From Male Hormone

These social, sexual, physical and mental conditions may be overcome by the use of the male sex hormones, which often bring about startling changes. At first, it may be noticed there is a marked improvement in physical and mental work and a tonic action resulting in renewed vigor. A better attitude towards business and social life is frequently observed. Nervousness, exhaustion and melancholy gradually disappear and in the large majority of instances the improvement persists over a long period of time.

Many excellent Reports for the Non Professional layman have already appeared in the following publications:

Readers Digest by Paul de Kruif, July, 1944—
August, 1946.

Newsweek, March, 1943.

Time, May 28, 1945.

Newsweek, May 28, 1945.

Liberty, February 2, 1946.

Paul de Kruif's sensational book, "The Male Hormone."



Just One Tablet a Day

15 Day Supply	\$ 6.00
30 Day Supply	10.00
90 Day Supply	24.00

Mailed in Plain Package

Send Check or Money Order

C.O.D.'s Accepted—Plus Postage

All Orders Sent Airmail

Same Day Received [386]



The Female Hormone

(A Estradiol)

The use of Female sex hormones usually brings prompt relief from such symptoms as hot flashes, emotional disturbances and other manifestations associated with the menopause. A steady readjustment may be obtained from the use of natural hormones, which help to overcome most menopausal conditions in women approaching or passing through this period.

Just One Tablet a Day

30 Day Supply	5.00
90 Day Supply	12.00

Mailed in Plain Package

Send Check or Money Order

C.O.D.'s Accepted—Plus Postage

All Orders Sent Airmail

Same Day Received

Relatively Safe

The Male and Female sex hormones as a rule are

relatively safe to use; however, they should be used cautiously by some individuals. The Female sex hormone should not be used by women with cancer or pre-cancerous lesions of the breast or genital organs and should be used with care by women with a family history of frequent incidence of breast or genital cancer. The Male sex hormone should be carefully used by elderly men with cardiovascular disturbances and should not be used if there is any indication of cancer of the prostate.

Caution: Take only as directed.

Hudson Products Co.

341 Harding St.

Long Beach 5, Calif. [387]

[Stamped]: 6-134 K July 16, 1948.

/s/ D. F. F.

[Initialed]: R. H. D. 7/16/48.

Count Three

(Continued)

(20642)

GOVERNMENT'S EXHIBIT 3(b)

Leaflet "The Story of Hormones" that accompanied drug, as received by Armond W. Welch of Seattle, Washington.

37-357/58 K

6-21-48 AMW

THE STORY OF HORMONES

Hudson Products Company, Long Beach, Calif.

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THE STORY OF HORMONES

Hudson Products Company, Long Beach, Calif.

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37-357/58K

How It All Began . . .

Far-reaching discoveries about male and female sex hormones are among the important achievements of modern medicine on which the general public is comparatively uninformed. Yet recent scientific research has established beyond doubt that treatment with hormones can bring about human benefits be-

lieved impossible until a few years ago.

As a result of incessant experiments with first the male and then the female hormones, science today assists millions of men and women to lead happier lives. Many conditions formerly thought to be inevitable with middle age can now be relieved.

For years certain scientists experimented with extracts and compounds of the sex hormones without satisfying results. Then, in 1935, came the first real step toward today's tremendous accomplishments with hormones—the isolation of a crystalline potent androgen from a bull's testes by a man named Laquer and his associates in Amsterdam. Laquer called the new substance "Testosterone." Today methyl testosterone is recognized as the most potent form of the male hormone.

Following Laquer's discovery a Swiss chemist, Prof. Ruzicker, succeeded in making testosterone by synthetic means. Ruzicker's work confirmed the structure of natural testosterone and won him the 1939 Nobel Prize in Chemistry. Androgenic (male hormone) therapy was thus removed from the realm of speculation and the unbiased scientific study of the physiologic and therapeutic activity of the sex hormone began in earnest.

How Hormones Affect Physical Development and Processes

From puberty to late middle life, and sometimes even in old age, the testes (stimulated by the anterior pituitary gland) produce appreciable amounts of the male sex hormone. Absorbed into the blood stream, which carries it to all parts of the body, the male

sex hormone has a variety of functions. For convenience they may be divided into four groups:

1. Influence on male reproductive organs
2. Influence on secondary sex characteristics
3. Influence on other endocrine glands
4. Influence on other organs, tissues and metabolic processes [400]

How Hormones Affect Male Reproductive Organs

The primary function of the male sex hormone is to regulate development and growth of the male reproductive organs. Even before a child is born, male sex hormone production is stimulated by the anterior pituitary gland of the mother-to-be, thus exerting its effect on the fetus.

Proper growth during puberty of the penis, scrotum, prostate, seminal vesicles, and Cowper's gland depends upon the presence of the androgenic (male) hormone. It may also be responsible for early descent of the testes. The male reproductive organs cannot function properly even after full development without an adequate supply of the male sex hormone. Sexual desire and potency are entirely dependent upon the amount and activity of the hormone.

How Hormones Affect Secondary Sex Characteristics

An increase of the androgenic hormone during puberty promotes development of secondary sex characteristics. Accordingly, in men, facial and

pubic hair appears. The masculine type of skeleton and muscles develop. Fat deposits are distributed in such a way as to form the masculine type figure. The voice deepens, and the masculine behavior pattern of aggressiveness, vigor, and self confidence also becomes evident. It is interesting to note that marked muscular development has been promoted in animals and in men by the therapeutic administration of the male sex hormone.

Concerning Male Disorders

The Male Climacteric or "Change of Life"

The climacteric in women is clearly defined because of cessation of menstruation. Since men do not menstruate, it was assumed for a long time that they did not have a climacteric. The male climacteric develops gradually, progresses slowly, and may occur relatively early or late in life. Thus it often represents a complex and confusing diagnostic problem.

During this transitional period of involutional gonadal changes, some men are subject to a variety of distressing and discouraging complaints which may seriously interfere with their capacity for work or enjoyment of leisure. Symptoms which are troublesome in one patient may be entirely absent in another, and concomitant complaints of non-hormonal origin may add to the diagnostic difficulties of a particular case.

Although manifestations of the male climacteric are most frequent in patients in their forties and fifties, (the average age in women is 40.8) the pos-

sibility of hormonal imbalance must not be overlooked in younger men. Cases in the fourth and seventh decades of life are by no means uncommon. For men from 50 to 65 who complain of vague and often apparently unrelated symptoms (and who under careful study reveal signs of the climacteric) use of methyl testosterone has been urged. [401]

Symptoms of the Male Climacteric

The discomfort men suffer during the climacteric results principally from subjective rather than objective symptoms. These symptoms are classified as (1) nervous, (2) circulatory, and (3) general.

Nervous Symptoms

Practically all patients who can be considered to be suffering from this condition have a feeling of nervous tension or "intense subjective nervousness. There is "inward tremulousness" which is aggravated by fatigue or excitement. Many are nervous and irritable to the extent that they are exceptionally hard to get along with. Ordinary small mishaps, arguments and annoyances which are normally of little importance occasion considerable nervous and mental disturbance. Many patients complain that they wake up at night and find their hands and arms, or feet and legs, numb. There may also be itching, prickling, or tingling of the skin. Headaches of the non-migrainous type often occur. The two types of headache which are most important from a diagnostic point of view are (1) those in which there is a feeling of great weight upon the

head or a feeling of pressure; and (2) those in which the pain may radiate to the neck over the back of the shoulders and down the spine. The latter type headache may last from a few hours to several days, often causing the patient to complain of a mental haziness for days.

A decrease in the ability to concentrate and faulty memory is frequently complained of, and depression or melancholia are often encountered. Intellectual changes in male climacteric patients have been described as "lack of interest in social and business life, lack of mental concentration and energy . . . a feeling of inadequacy or impotency. Occasionally the individual conceives himself to be useless, hopeless and burdensome."

Circulatory Symptoms

Hot flashes occurred in about a third of recent case studies. They are usually of short duration but are very uncomfortable and patients sometimes compare them to feelings of smothering. They may be accompanied by sweating and chilly, creepy sensations.

General Symptoms

This group of symptoms includes tiring easily, decrease in potency and libido, constipation and the tendency to gain excessive weight.

Vague digestive complaints and precordial, angina pectoris-like pains may also be outstanding symptoms. Urinary symptoms, such as frequency, nocturia, dribbling and inability to start urinary stream are invariably associated with changes in the prostate and seminal vesicles.

Treatment for Male Climacteric

The gratifying effectiveness of replacement therapy with male hormones in the male climacteric has been confirmed by a large number of observers. Adequate hormone therapy produces in many cases "genuinely desirable results." Patients who have feared they might be mental cases because of depression and nervous instability gradually regain confidence in their mental reactions and decisions. Patients usually report that they regain their grip on life shortly after the start of treatment, and their capacity for mental and physical work is often notably increased. [402]

Impotence

As has already been mentioned, decreased sexual desire or complete impotence may accompany the male climacteric, though it may occur also at other times. Indeed, adequate sexual competence depends upon the integrated co-operation of several factors. Anatomic, hormonal, neurologic, psychologic, and emotional components are involved in the attainment of full potency. Impotence may be caused by a disturbance of one or several of these factors.

When impotence is caused by male sex hormone deficiency, replacement therapy with methyl testosterone is indicated. In most cases this will restore sexual desire, potency and genital tract tone with adequate sexual competence. At the same time there is often an improvement in physical and mental mal-conditions. Methyl testosterone is especially

beneficial in young and middle aged men with diminished potency, who were formerly normal.

The Female Hormone

Women, too, can find extraordinary benefits in the therapeutic administration of the sex hormone. Prompt relief is obtainable from such unpleasant menopause disturbances as hot flashes, emotional upsets and other "change of life" manifestations. A steady readjustment may occur through the use of the natural hormone, which helps overcome most menopausal conditions in women approaching or passing through this period.

Hormonal Treatment for Breast Development

Small or undeveloped breasts are frequently a cause of worry to some women. In the form of a specially prepared and medically approved ointment, the female sex hormone used for therapy produces a direct action on the mammary gland. Applied directly to the breast, this hormonal ointment stimulates growth considerably, yet helps retain the pointed shape of the young breast. The desired stimulation results from a re-vitalized concentration of the sex hormone in the body tissue. Marked results are obtainable after 60 to 90 days use.

25 Day Supply of Ointment

(125,000 International Units) \$12.95

2½ Month Supply of Ointment

(375,000 International Units) \$33.95

Warning

Although both male and female sex hormones are relatively safe to use as a rule, scientific tests prove that they should not be used by anyone suffering from cancer. Neither should they be used by persons suffering from serious heart trouble. Also, hormone therapy should be used with caution by senile men in whom excessive stimulation of waning sex power may be physiologically undesirable. [403]

New Low Prices

The Male Hormone

30 day supply.....	10.00
90 day supply.....	30.00

The Female Hormone

30 day supply.....	\$ 5.00
90 day supply.....	15.00

Mailed in plain package Air Mail same day order received. Send cash, check or money order.

C.O.D. you pay postage



Hudson Products Co.

341 Harding St.

Long Beach 5, Calif. [404]

COUNT FOUR

Government's Exhibit 4. Label on carton of drug as received by Armond W. Welch of Seattle, Washington.

(20642)

Female Hormones

(30) 0.1 Mg. Cryst. a-Estradiol

Important: In case of pronounced female sex hormone deficiency take 3 tablets daily before meals for 10 days. After the 10-day period take 1 tablet daily or as directed by your physicians.

Warning: The female hormone should not be used by women with cancer or pre-cancerous lesions of the breast or genital organs.

Not for use by children. Caution—take only as directed.

Hudson Products Co.

341 Harding St., Long Beach 5, Calif.

37-358 K 8-6-48 A. M. W.

[In Longhand]: Opened 8/20/48 J.P.G.

Received 8/13/48

[Endorsed]: Filed July 7, 1949.

[Title of District Court and Cause No. 10391-HW]

CERTIFICATE OF CLERK

I, Edmund L. Smith, Clerk of the United States District Court for the Southern District of California, do hereby certify that the foregoing pages numbered from 1 to 420, inclusive, contain the original Complaint for Injunction; Separate Affidavits

of Clinton Hobart Thienes, Elmer Belt, and Ian Macdonald; Order Granting Temporary Restraining Order; Affidavit of Robert S. Roe; Order to Show Cause; Stipulation, Consent and Order filed Sept. 7, 1949; Amendment to Complaint for Injunction; Stipulation, Consent and Order filed Oct. 3, 1949; Answer of Defendant Martin A. Clemens et al; Affidavit of Eugene M. Elson; Affidavit of Martin A. Clemens; Supplemental Affidavit of Martin A. Clemens filed Oct. 24, 1949; Supplemental Affidavit of Martin A. Clemens filed Nov. 1, 1949; Affidavit of Lewis A. Schinazi; Stipulation and Order Permitting Filing of Amendment to Answer; Amendment to the Answer; Stipulation and Order filed Jan. 17, 1950; Affidavit of Walter F. McRae; Affidavit of Albert H. Wells; Supplemental Affidavit of Robert S. Roe; Findings of Fact and Conclusions of Law on Prayer for Preliminary Injunction; Stipulation as to Record; Findings of Fact and Conclusions of Law; and Judgment in the case numbered 10266-HW-Civil; Complaint for Injunction; Order to Show Cause; Affidavit of Robert S. Roe; Stipulation Regarding Medical Affidavits; Stipulation and Order for Continuance filed Oct. 21, 1949; Answer of Hudson Products Company et al; Affidavit of Allen H. Parkinson; Stipulation and Order Permitting Filing of Amendment to Answer; Amendment to the Answer; Stipulation and Order filed Nov. 10, 1949; Findings of Fact and Conclusions of Law on Prayer for Preliminary Injunction; Stipulation as to Record filed Jan. 31, 1950; Stipulation as to Record filed April 14, 1950; Findings

of Fact and Conclusions of Law; and Judgment in the case numbered 10391-HW-Civil; Information and Stipulation of Facts in case No. 20596-Criminal entitled United States of America, plaintiff, vs. El-O-Pathic Pharmacy, Inc., et al, Defendants; Information and Stipulation of Facts in case No. 20642-Criminal entitled United States of America, plaintiff, vs. Allen H. Parkinson etc., Defendant; Notice of Appeal; Statement of Points on Appeal and Designation of Record in Appeal in cases Nos. 10266-HW and 10391-HW; and full, true and correct copies of minute orders entered January 31, 1950 and February 3, 1950 in cases Nos. 10266-HW and 10391-HW; which, together with copy of reporter's transcript of proceedings on March 22, 1950 in cases Nos. 10266 and 10391-HW; copy of reporter's transcript of proceedings on June 22, 23, 24, July 5, 6, 7, 8 and 13, 1949 in case number 20596-Criminal and original plaintiff's exhibits Nos. 1 to 25, inclusive, and original defendant's exhibits A to L, inclusive, and original Parkinson exhibit A in case No. 20596-Criminal, transmitted herewith, constitute the transcript of record on the appeals in cases numbered 10266 and 10391-HW to the United States Court of Appeals for the Ninth Circuit.

Witness my hand and the seal of said District Court this 25 day of August, A.D. 1950.

EDMUND L. SMITH,
Clerk.

[Seal] By /s/ THEODORE HOCKE,
Chief Deputy.

[Endorsed]: No. 12665. United States Court of Appeals for the Ninth Circuit. United States of America, Appellant, vs. El-O-Pathic Pharmacy, Martin A. Clemens, Hudson Products Company, Maywood Pharmacal Company and Allen H. Parkinson, Appellees. Transcript of Record. Appeal from the United States District Court for the Southern District of California, Central Division.

Filed: August 26, 1950.

/s/ PAUL P. O'BRIEN,

Clerk of the United States Court of Appeals for the Ninth Circuit.

United States Court of Appeals
for the Ninth Circuit

No. 12665

UNITED STATES OF AMERICA,

Appellant,

vs.

EL - O - PATHIC PHARMACY, a corporation,
MARTIN A. CLEMENS, an individual, and
VITA PHARMACALS, INC., a corporation,
Appellees.

UNITED STATES OF AMERICA,

Appellant,

vs.

HUDSON PRODUCTS COMPANY, a corporation,
and its subsidiary firm doing business under
the fictitious name and style, MAYWOOD
PHARMACAL COMPANY, and ALLEN H.
PARKINSON, an individual,
Appellees.STATEMENT OF POINTS ON WHICH AP-
PELLANT INTENDS TO RELY ON THE
APPEAL

Appellant hereby states the points upon which
it intends to rely on appeal:

(1) The District Court erred in holding that the
labeling of appellees' drugs bears adequate direc-
tions for use, within the meaning of 21 U.S.C.352
(f)(1).

(2) The District Court erred in holding that the labeling of appellees' drugs bears adequate warnings, within the meaning of 21 U.S.C. 352(f)(2), against use in those pathological conditions where their use may be dangerous to health.

(3) The District Court erred in holding that appellees' drugs are not dangerous to health, within the meaning of 21 U.S.C. 352(j), when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling.

(4) The District Court erred in holding that the labeling of appellees' drugs [the 5-milligram methyl testosterone linguets, and the combination methyl testosterone and Vitamin B₁ linguets] is not false or misleading within the meaning of 21 U.S.C. 352(a).

(5) The District Court erred in holding that appellant failed to establish that the daily intake of 5 milligrams of methyl testosterone in linguet form is ineffective in the treatment of male hormone deficiency.

(6) The District Court erred in holding that appellees' drugs are not misbranded within the meaning of 21 U.S.C. 352(a), (f)(1), (f)(2), and (j).

(7) The District Court erred in holding that appellant failed to sustain its burden of proof.

(8) The District Court erred in refusing to issue permanent injunctions as prayed to restrain the

appellees from further violations of the Federal Food, Drug, and Cosmetic Act.

Respectfully submitted,

ERNEST A. TOLIN,
United States Attorney,

CLYDE C. DOWNING,
Asst. U.S. Attorney,

/s/ GEORGE E. DANIELSON,
Asst. U.S. Atty.

Attorneys for United States of America, Appellant.

Affidavit of Service by Mail attached.

[Endorsed]: Filed August 30, 1950.

No. 12,665.

IN THE

United States Court of Appeals

FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA,

Appellant,

vs.

EL-O-PATHIC PHARMACY, a corporation, MARTIN A. CLEMENS,
an individual, and VITA PHARMACALS, INC., a corporation,

Appellees.

UNITED STATES OF AMERICA,

Appellant,

vs.

HUDSON PRODUCTS COMPANY, a corporation, and its subsidiary firm
doing business under the fictitious name and style, MAYWOOD PHAR-
MACALS COMPANY, and ALLEN H. PARKINSON, an individual,

Appellees.

On Appeal From the United States District Court for the
Southern District of California Central Division

BRIEF OF APPELLEES.

FILED

EUGENE M. ELSON,

541 South Spring Street, Los Angeles 13,

Attorney for Appellees.

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No. 12,665.

IN THE

United States Court of Appeals

FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA,

Appellant,

vs.

EL-O-PATHIC PHARMACY, a corporation, MARTIN A. CLEMENS,
an individual, and VITA PHARMACALS, INC., a corporation,

Appellees.

UNITED STATES OF AMERICA,

Appellant,

vs.

HUDSON PRODUCTS COMPANY, a corporation, and its subsidiary firm
doing business under the fictitious name and style, MAYWOOD PHAR-
MACALS COMPANY, and ALLEN H. PARKINSON, an individual,

Appellees.

BRIEF OF APPELLEES.

PRELIMINARY STATEMENT.

Appellees accept the statement of jurisdiction in Appellant's brief, without, however, admitting by inference or otherwise that the trial court was in error in denying the Government's application for a preliminary injunction. These cases are not, as Appellant would have it, "an offshoot of previous criminal cases involving the same defendants," as stated on page 2 of Appellant's Brief. There were criminal actions previously instituted against defendants involving labeling wholly foreign and entirely different from any of the labeling before this court. These criminal cases resulted in a judgment of conviction and the imposition of nominal fines *because of the labeling involved* in each case. As will be pointed out later in this brief, following the judgments in those cases the labeling was completely revised and it is that labeling which is the subject of the injunction cases which are before this court.

It was stipulated in both cases "in order that this case may be disposed of as quickly as possible" [R. 150, 266], the record in the court below should consist of the affidavits filed in these injunction actions as well as the informations and transcript of testimony, including exhibits in the criminal cases.

As will be shown, in view of the issues raised by the pleadings in these cases, the court was called upon to determine from the record, included in the stipulations above referred to, whether by force of that evidence the Government had sustained its burden of proof *with respect to the labeling involved herein*. It is not true, as Appellant has stated on page 34 of its brief, that the refusal of the court to grant a permanent injunction against the defendants "has nullified the convictions in the criminal cases." We repeat again—the convictions in the criminal cases were based upon the labeling before the court there which was wholly different than that before the court in this case.

The labeling in the *Parkinson* criminal case contained a warning statement. No charge was made in that case that it was insufficient. The labeling in the *El-O-Pathic* case did not involve a warning statement and the court decided that that fact misbranded the drug.

It was not contended in either of those cases (as it is now) that under a proper interpretation of the Federal Food, Drug and Cosmetic Act, the drugs here involved may not be sold except upon prescription. That point is argued for the first time in these injunction cases and it is significant that if the Government were sincere in their theory as it now comes to light, the charge would have been made in the informations in the criminal cases, as well as in the Complaints in these injunction cases; that the Act

was violated in that these drugs were sold without a prescription. This contention was not made nor was it pleaded for the very obvious reason that there is nothing in the Act which provides that it is violated if certain drugs are sold without a prescription. As we shall point out, the only requirement so far as pertinent here is that the labeling shall bear adequate directions for use and shall bear adequate warnings. If this requirement is complied with, the authority is not given the Government to contend as they do here that the directions for use are inadequate and the warning statements are inadequate because, in the opinion of the Government, a drug should only be sold on prescription and therefore no directions for use or warning statements can be adequate and that whether or not an individual has sought to exempt himself from the requirement that he state adequate directions for use and gave adequate warnings he must nevertheless come within the exempted class if in the opinion of the Food and Drug Administration he should be exempt.

We have prepared as an appendix to this brief a résumé of the pleadings and the evidence which was before the trial court, in these injunction cases so far as it is pertinent to the questions which this court is called upon to determine. We have stated it in narrative form as we believe it much easier reading set out in that fashion than simply to refer the court to the record in which the evidence appears in question and answer form. Also in the Appendix will be found the legislative history of the provisions of the Act here in question and the so-called "Durham-Humphrey Bill" pending in Congress, which bill seeks to give the Food and Drug Administration the authority they contend in this case the Act already gives them.

II.

STATEMENT OF THE CASE.

A. THE PLEADINGS.

1. THE PLEADINGS IN CASE No. 10266-HW (THE EL-O-PATHIC OR CLEMENS CASE).

The complaint alleges that the defendants distributed methyl testosterone tablets, 10 milligrams and 25 milligrams, and in linguet form, 5 and 10 milligrams, and various preparations of female hormone drugs [App. 1; R. 3]. The labeling used is set forth in full in the Appendix [App. 1-2; R. 4]. It was charged that the shipment in interstate commerce of these drugs constituted a violation of Section 502(f)(1) of the Act (21 U. S. C. 352(f)(1)) in that the labeling failed to bear adequate directions for use in failing to state all of the diseases or conditions for which the drug was contended; that Section 502(f)(2) of the Act (21 U. S. C. 352(f)(2)) was violated in that the labeling failed to bear adequate warnings against use in certain pathological conditions where its use may be dangerous to health; that Section 502(j) of the Act (21 U. S. C. 352(j)) was violated in that the product was dangerous to health when used in the dosage and with the frequency prescribed, etc., in the labeling [App. 3; R. 6]; that Section 301(a) of the Act (21 U. S. C. 351(a)) was violated because the 5 milligram linguets were ineffective for the treatment of a male hormone deficiency [App. 3; R. 7].

The answer in substance denied all of the material allegations of the complaint and attached to it as Exhibit "A" the labeling employed [App. 4; R. 35].

2. THE PLEADINGS IN CASE NO. 10391-HW (THE HUDSON PRODUCTS COMPANY OR PARKINSON CASE).

The complaint in this case was essentially the same as in Action No. 10266-HW [App. 4]. However, no temporary restraining order was applied for and it was not alleged that these defendants sold the 25 milligram product. The answer in this case in substance denied the allegations of the complaint [App. 4; R. 179].

B. THE FACTS.

On page 2 of Appellant's brief, the so-called "medical facts" are stated which Appellant would have this court believe were the medical facts before the court below. Appellant has adroitly omitted, however, to state any of the medical facts except those which they apparently believe to weigh in their favor. The court below, however, had before it *all* of the testimony and decided that the Government had not sustained its burden of proof.

This testimony before the lower court is set out in the Appendix to this brief. The trial court after reviewing all of this evidence in the light of the issues framed by the pleadings, and in the light of the labeling involved in these injunction actions, decided that the directions for use contained on this labeling were adequate, that the warning statements were adequate and that the plaintiff had failed to sustain the burden of proof of showing that they were inadequate.

By stipulation in the consolidated injunction cases [R. 150, 266], the record before the trial court consisted of the affidavits referred to in the Appendix to this brief, and the testimony in the transcript of the trial in the criminal proceedings, which testimony is set forth in narrative form on pages 8-42, 61 of the Appendix.

Robert S. Roe, Chief of the Los Angeles District of the Food and Drug Administration, executed an affidavit in Case No. 10266-HW, attaching a letter from one of the manufacturers of the product involved, addressed to all distributors of the product and which was received by the defendants in that action and concludes that these defendants were warned thereby of the “dangers” incident to the sale of the product without prescription [App. 5; R. 20].

With reference to Action No. 10391-HW—the Hudson Products case—it was stipulated that none of the evidence in the transcript of testimony pertaining to the alleged “danger” of using testosterone was introduced as against the defendants in that action at the criminal trial and no charge was made by the Government in that action that the warning statements on the labeling involved in that action—No. 20642, Criminal—was inadequate [App. 6; R. 266].

The testimony of Dr. Thienes appears in the transcript of testimony [App. 8; R. 344]. In substance that testimony was that it is the consensus of opinion as he understands it, and his opinion, that testosterone may accelerate the growth of cancer of the prostate and may induce sterility, that it is ineffective in the treatment of certain symptoms or conditions unless they are caused by a male hormone deficiency, which is a very rare condition, and that he believes that the general practitioner today would conduct detailed tests to determine whether that condition existed before prescribing the product. To avoid unnecessary repetition, we refer the court not only to the testimony of Dr. Thienes, but as well to all of the facts set forth in the Appendix.

Dr. Warren Nelson [App. 10; R. 396], connected with the University of Iowa, had conducted tests to determine the effect of testosterone on fertility. He stated that there was a possibility of testosterone decreasing fertility and this conclusion was drawn from experiments made by him at the University; also that the method of approach used by those in experimental institutions was considerably different than the approach employed by the general practitioner.

Dr. Heckel [App. 12; R. 463], likewise stated that testosterone would, in his opinion, accelerate the growth of a cancer of the prostate, but he stated that it would also cause sterility contrary to what Dr. Nelson stated; that testosterone is of immeasurable value in the treatment of flushes, sweats and all of the symptoms and conditions called to his attention, provided that they were caused by a male hormone deficiency which, in his opinion, was very rare and he did not know how to diagnose it; that the incidence of the male climacteric was a very rare thing. He went into great detail concerning the elaborate tests that were necessary before prescribing testosterone and stated that if after making all of these tests a general practitioner found nothing to contra-indicate the use of testosterone "*he might but he shouldn't*" suggest the product to the patient for a period of time to see whether he was relieved.

Dr. Belt [App. 15; R. 514], is a urologist and stated that in his opinion methyl testosterone will accelerate the growth of a cancer of the prostate and he gave instances which he stated in his opinion cancer of the prostate was accelerated in growth by the drug. In many instances it is very valuable but elaborate tests concerning which he went into great detail were necessary as a prerequisite

except in the cases of young individuals known as hypogonads, or in the case of castrates, but that even after a careful examination of the patient, with no indication of cancer of the prostate present, it would still be dangerous and conducive to the development of such a cancer for the individual to take it. If a person called upon a general practitioner and complained of the various symptoms referred to by him before prescribing testosterone, he would think about the problem and if he thought much about it he wouldn't prescribe it. There would be no blood tests to determine the presence of cancer unless he wished to do the acid and alkaline phosphatase test and the urine test would not show anything unless he wished to take the 17 ketosteroids test which consumed a period of about a week to complete. The problem of hormone deficiency is that of the general practitioner and the middle aged man who is tired and worn out and comes to see the doctor for help is his "meat." He does not think that there is such a thing as the male climacteric and believes that most careful observers are of the same opinion, though it is not universally shared by the profession.

Dr. Charles Huggins [App. 18; R. 540] is a professor of urology at the University of Chicago and is a professional investigator. He does not believe that a male hormone deficiency occurs except in people who are hypogonads or castrates. He believes that it will accelerate the growth of cancer of the prostate. The ordinary physician is not capable of conducting blood tests but a hospital is. There is a difference of opinion on the subject in medical circles whether there is such a thing as the male climacteric and many articles are found in the literature in which the subject is discussed, but he does not agree with those investigators. His attention was called to three articles

by different doctors appearing in various scientific journals. He disagreed with all and, as to one, he stated that the statements of the author were "absurd."

As shown by the facts in the Appendix, pages 21-27; 28-30, inclusive, Drs. Belt and Heckel did not in actual practice give the tests nor do what they said was necessary prior to prescribing testosterone. The impeaching testimony of these doctors was given by three individuals whose testimony appears on pages 21, 27 and 28 of the Appendix. The effort of these doctors to rebut that impeaching testimony will be stated here in order that a full appraisal may be given at the same time by the court.

Allen H. Parkinson went to Dr. Belt's office the day after Dr. Belt testified as above related, stated that he had been referred to that office by a doctor in Salt Lake, that he had been troubled with diminishing of the testes and penis and wanted some testosterone. Dr. Belt interviewed him, and a blood and urine sample was taken. He was injected with 50 milligrams of testosterone, was asked by Dr. Belt how many tablets of testosterone he wished and obtained a prescription for 100 ten milligram tablets, was told that the charge was \$5.00, which he paid [App. 21; R. 866].

Dr. Belt then gave him a brief rectal examination and that was all of the examination given.

On rebuttal Dr. Belt stated that if a person comes to him from another doctor for some drugs, he always allows the other physician the benefit of whatever doubt might exist in his mind and he goes on with the original treatment until he is able to communicate with the doctor and discuss the problem with him [App. 22; R. 692, 938]. He stated that he examined Parkinson on the day men-

tioned by the latter and testified from notes as to the examination given, and that Parkinson had said that another doctor had referred him and he asked for a prescription of 10 milligrams of the product. He said that he made a complete physical examination; examined his eyes, pupils, his pharynx, his teeth, felt his thyroid, examined his thorax, took his blood pressure, determined his pulse rate and rhythm, felt his abdomen, looked at his extremities, tapped his reflexes. The notes from which the doctor was reading were read into evidence and we refer the court thereto [App. 25; R. 943], where it will be noted no reference was made to any of the tests which the doctor stated he had given.

Hannah Shinglman went to Dr. Belt's office in Beverly Hills, which was the Elmer Belt Urological Group. Dr. Norman LeTourneau was one of the members of this group. She asked to see Dr. Belt, was told that he was not there and was referred to Dr. LeTourneau. She told him that her husband had come from Chicago and that a doctor in that city had been giving him testosterone as her husband was going through the male change. Her husband was not with her. Dr. LeTourneau gave her a prescription for those tablets and she left [App. 27; R. 892].

On rebuttal Dr. LeTourneau admitted giving the prescription to her and that her husband was not present [App. 28; R. 947].

Hazen S. Parkinson arrived in Chicago June 27, 1949, shortly after Dr. Heckel had testified in this case. He asked to see Dr. Heckel, showed him a bottle the label of which indicated that it had contained 500 five milligram linguets of testosterone and told him he wanted a refill,

that he was going on a ship and would be gone for a long time [App. 28; R. 898]. Nothing was said by the doctor on the subject of fertility. He had Mr. Parkinson urinate in a glass and placed his finger in Mr. Parkinson's rectum and then wrote out the prescription. He told the doctor that he wanted 500 tablets because some of the men on the ship on which he was going would like to have some. He was in the doctor's office five or six minutes. At the time of his visit he was 65 years old and told the doctor that he wanted enough testosterone for a year. The prescription written by the doctor was for 500 five milligram linguets.

In the interests of saving time, counsel for the defendants stipulated with the Government that if Dr. Heckel were called on rebuttal he would testify in accordance with the letter sent by him to Government counsel following Mr. Parkinson's visit to him, which stipulated in part that Mr. Parkinson came to his office in Chicago [App. 30; R. 923] and stated that he had been referred to by a former patient. Parkinson said that he was 72 years of age, a sailor by occupation and gone from the country for long periods of time; that his doctor in Salt Lake City had been giving him a prescription for methyl testosterone and that he had been taking this drug under his doctor's direction for the past several years. Dr. Heckel then made a physical examination of Parkinson, which included a urine analysis and a rectal examination of the prostate and found no contraindication to the use of testosterone.

Allen H. Parkinson and Hazen S. Parkinson [App. 31; R. 870, 902, 269] both testified that during the course of the trial in the criminal action they called upon general practitioners, asked for and received a prescription for

testosterone linguets. Allen H. Parkinson called on one and Hazen S. Parkinson called on fifteen doctors located in the metropolitan areas in Los Angeles and Long Beach; that they were not refused the requested prescriptions from any doctor upon whom they called and that none of the doctors so much as laid a hand upon either prior to writing out the prescription.

Dr. William A. Swim [App. 34; R. 835] a defense witness, has been practicing in Los Angeles for thirty years, specializing in internal medicine and was formerly a member of the Board of Medical Examiners of California; he has found many males in middle life who suffer from symptoms which he described and which he associates with the male climacteric; in connection therewith he prescribes testosterone to see whether the symptoms are relieved. He has never encountered any adverse results from the use of the product. He does not conduct the elaborate tests referred to by the Government witnesses prior to prescribing the product and knows of no other doctor who does so. He prescribes it about once a week and he knows of no instance in which a biopsy of the testes is conducted to determine the effect of testosterone, except possibly in experimental institutions.

Dr. George E. Fakehany [App. 37; R. 740], a defense witness, graduated with the degree of M. D. *cum laude*. He is medical consultant for Technicolor Motion Picture Corporation, Samuel Goldwyn Studios and Radio Corporation of America. He does not conduct the elaborate tests mentioned by the Government witnesses prior to prescribing testosterone and has had no adverse results from the use of the product. The literature as to whether testosterone will accelerate the growth of such a cancer

is in confusion and the views of the investigators are not uniform. When a man calls upon him and complains of the symptoms referred to by all of the witnesses, he prescribes testosterone for a period of time to see whether he is relieved. He knows of no doctors in this locality who give the tests mentioned by the Government witnesses.

Dr. Paul E. Travis [App. 39; R. 788], a defense witness, graduated from the University of Southern California, Phi Beta Kappa. Was in the service for two years in the Veterans Hospital, Arizona, and used testosterone at that hospital for men who complained of the symptoms subject of all of the witnesses. He does not, and knows of no other doctors in general practice who conduct the elaborate tests testified to by the Government witnesses and he has never encountered any adverse results in the use of the product. He has read the literature on the subject and as to the effect of testosterone in its relationship to cancer of the prostate are confusing and the articles are pro and con on the subject.

An affidavit was filed [App. 42; R. 55] by the defendant, Martin A. Clemens, and his affidavit is part of the record under the stipulation referred to, in which he stated the vast number of tablets of testosterone sold by him. He also set forth the reasons for revising the label following the judgment in the criminal action so as to conform to the evidence of the Government witnesses and thus meet any objections made by the Government to the labeling of such a product. He quoted from standard medical works, including the United States Pharmacopoeia, showing that the dosage for testosterone recommended by those publications was 5 milligrams, this to refute the Government's contention that 5 milligrams had no therapeutic value.

Allen H. Parkinson likewise filed an affidavit [App. 47; R. 199] which under the stipulation mentioned was part of the record before the trial court. He likewise analyzed the counts in the information in the criminal action against him and the reason for the complete relabeling of the product so as to conform to the objections made by the Government during the course of the criminal trial. He also referred to the recommended dosage from standard medical works such as was done in the Clemens affidavit. He then referred to circulars mailed by him to retail druggists following the revised labeling and an exchange of correspondence between the Southern California Pharmaceutical Association and the Chief of the Los Angeles District of the Food and Drug Administration while the injunction suit against him was pending and pointed out that in the letter from the said Chief the view was expressed that the sale of this product, regardless of the labeling, violated the Food and Drug Act but no mention being made of the pendency of the case in which that question was in issue.

Eugene M. Elson, defense counsel, filed an affidavit [App. 53; R. 49] setting forth excerpts from the file in an action, *United States v. Walter Kurt Max Hassenstein*, No. 19004, Criminal, in the United States District Court, the purpose of this affidavit being to bring before the court a prior case in which labeling somewhat comparable to that involved herein was approved by the court as bearing adequate directions for use and warnings.

Rebuttal evidence offered by the plaintiff consisted of affidavits of employees of the Food and Drug Administration and the testimony of one doctor. One of these affidavits concerned purchases in August, 1949, from the place of business of the defendant, Vita-Pharmacals, and

the request of the salesman that he furnish his name and address in order that he might be informed as to new products [App. 57; R. 120]. A similar affidavit was executed by Albert H. Wells [App. 58; R. 131], a chemist of the Food and Drug Administration, concerning purchases by him in November, 1949. A supplemental affidavit was executed by Robert S. Roe [App. 58; R. 136] concerning investigations to determine whether the revised labeling caused purchasers to consult physicians before taking the drug and attaching thereto affidavits of individuals interviewed.

An affidavit was executed by Walter F. McRae [App. 59; R. 126], acting Chief of the Los Angeles District, Food and Drug Administration, in rebuttal to a supplemental affidavit of the defendant, Clemens, concerning certain patent medicines and alleging that a seizure action was pending against one of these products and that another was under investigation, that the State Board of Pharmacy in January, 1950, had been requested to hold hearings and classify testosterone as a dangerous drug in California, to be sold only under prescription.

Dr. Elwyn Terrill [App. 61; R. 924] testified in the criminal actions that he was in general practice and did not prescribe testosterone except after giving detailed examinations and that he knows of no doctors in his circle of acquaintances who prescribe it without such examinations.

It was stipulated at the trial of the criminal actions that both parties could produce additional general practitioners who would serve to corroborate the testimony of the defense witnesses and others to corroborate the testimony of Dr. Terrill [App. 33; R. 929].

C. THE QUESTIONS INVOLVED.

We do not concur in the statement of the questions involved as set forth in Appellant's brief. The questions thus stated assume facts contrary to those found by the trial court. The facts assumed in Appellant's questions were the facts which were unsuccessfully contended for by Appellant in the trial court. We conceive the questions involved to be as follows:

1. Is Section 502(f)(1) of the Act (21 U. S. C. 352 (f)(1)) susceptible of the interpretation that the Food and Drug Administration may not only *exempt* certain drugs from the requirement that they bear "adequate directions for use," but as well determine that for some drugs adequate directions for use cannot be composed and *restrict* the sale of such drugs to sale by prescription only.

2. Does the evidence support the finding that the labeling involved herein bears adequate directions for use within the meaning of Section 502(f)(1) of the Act (21 U. S. C. 352(f)(1)).

3. Does the evidence support the finding labeling involved herein bear adequate warnings as required by Section 502(f)(2) of the Act (21 U. S. C. 352(f)(2)).

4. Does the evidence support the finding that methyl testosterone, tablets and linguets of 5, 10 and 25 milligrams, are not dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended or suggested in the labeling within the meaning of Section 502(j) of the Act (21 U. S. C. 352(j)).

5. Does the evidence support the finding that the labeling involved does not violate Section 502(a) of the Act (21 U. S. C. 352(a)) in that methyl testosterone linguets of 5 milligrams does have therapeutic value in the treatment of a male hormone deficiency.

III.

SUMMARY OF ARGUMENT.

The trial court found the directions for use and the warning statements to be adequate and in compliance with Section 502 (21 U. S. C. 352) of the Act [R. 158, 274], that there was medical opinion on both sides as to whether there were ill-effects from the taking of these drugs, that they were not dangerous to health when taken as directed in the labeling and that the plaintiff had not sustained its burden of proof with respect to the allegations in effect [R. 158, 274].

The medical opinion appearing in the record, taken in connection with the conclusive impeachment of two of the Government witnesses, was convincing that medical opinion amongst professional investigators and experimenters is divided as to whether testosterone may accelerate the growth of cancer of the prostate or produce a temporary degree of fertility.

The individual who complains of the symptoms usually associated with the male climacteric, *i. e.*, flushes, sweats, nervousness, inability to concentrate on activities and a tendency to evade them, etc., invariably calls upon the doctor in general practice who does not associate with these drugs the danger to his patient in the particulars mentioned or conduct other than the most cursory examination before prescribing them.

The individual purchasing such a drug, labeled as the products here involved were labeled, is afforded directions for use and warnings, if any are needed, far more adequate than he would obtain from the general practicing doctor upon whom he would call.

Section 502(f) of the Act (21 U. S. C. 352(f)) simply requires that all drugs be labeled with adequate directions

for use and adequate warnings. This section, as shown by the legislative history preceding its adoption, means that with appropriate directions for use and adequate warnings, a drug may be sold without the actual prescription of a physician and that the Act is not susceptible of the interpretation as contended for by Appellant, that if the Food and Drug Administration should decide that a particular drug should not be sold except on prescription, that person must then come within the exemption mentioned in Section 502(f) and comply with the regulations which would exempt him from the requirement that his labeling bear adequate directions and warnings for use whether or not he has applied for or sought to come within the exempted class.

The administrative interpretation adopted by the Food and Drug Administration with respect to directions for use and warnings, viewed in connection with products which have been on the market for many, many years, involves the conclusion that the directions for use and the warnings on the labeling involved herein are adequate and comply with the provisions of the Food and Drug Act. The contention of the Government that the Food and Drug Administration may determine not only the manner in which a drug must be labeled, but whether it may be labeled at all, and whether it must be sold solely under prescription, is not only contrary to the intent of Congress but attempts to vest in that administration the power to select any drug, *i. e.*, aspirin or simple laxatives, and decree that they may only be sold upon prescription.

The authority contended for by the Appellant in this case is precisely the authority sought by S. 3852—the Durham-Humphrey Bill—included in the Appendix to this brief, and introduced in June 1950, at the 81st Congress, Second Session, one of the supporters of the bill being the Food and Drug Administration.

IV.

ARGUMENT.

A. SCOPE OF REVIEW.

The Government takes the position on page 35 of their brief that the scope of review by this court is “*de novo*” since the judgments of the district court were based entirely upon a stipulated written record.”

It seems to us that it hardly lies with the Government to advance an argument of this kind when one considers that the stipulations as to the record [R. 150, 266] were entered into in order that these cases “may be disposed of as quickly as possible.” It was agreed between both counsel that if oral testimony was to be adduced, the same witnesses who had testified in the preceding criminal cases would be called upon to testify and to a large extent their testimony would be the same. This was considered to be a needless waste of time and expense, hence the stipulation. There was no thought in the mind of counsel for the defendants, and certainly in the open discussions preceding the preparation of these stipulations no intimation whatever was made by counsel for the Government that it was intended that the review by this court should be any different than a case where findings had been made upon oral testimony.

Be that as it may, *Equitable Life Assurance Society v. Irelan*, 123 F. 2d 462 (9th Cir., 1941); *Stork Restaurant Inc. v. Sahiti et al.*, 166 F. 2d 348 (9th Cir., 1948), and *Murphy et al. v. United States*, 179 F. 2d 743 (9th Cir., 1950), involved *depositions*. *Orvis v. Higgins*, 180 F. 2d 537 (2nd Cir., 1950) involved, for the most part, *undisputed facts*. *Blackner v. McDermott*, 176 F. 2d 498 (10th Cir., 1949) involved *stipulated facts*, and *United States v.*

United States Gypsum Co. et al., 333 U. S. 364 (1947), involved *documents and undisputed facts*.

In the instant case, the facts are neither stipulated to, nor are they depositions, nor does the case depend upon documents and certainly they are not undisputed. In our search we have found no similar case where it has been held that the Appellate Court need not give any weight to the findings of the trial court. The trial court in the instant case was called upon to read approximately 800 pages of reporter's transcript of testimony, which testimony was in sharp conflict in many particulars. Upon the basis of that study the court found that "there is medical opinion on both sides as to whether there are ill effects from taking said drug" [R. 158] and upon the record before it the Act was not violated by the defendants in these injunction cases. It would certainly seem (if the rule is that contended) as a matter of common sense that all of the time and expense utilized in the trial court was a mere waste of time; the study given by the trial court to the record and his findings and conclusions meant nothing and that this court is called upon to do what the trial judge did and review the entire record as though it were sitting as a trial court in the first instance. We do not believe that this court will be willing to announce that the rule in the cases cited by the Government applies in a case such as this.

The contention made by the Government that this proceeding must be heard *de novo* is clearly erroneous and apparently the Government has confused the rule in admiralty with what they contend the rule to be here. The rule in admiralty is that upon appeal the case is open for a trial *de novo* and even in such cases the findings of the

trial court, when based upon the depositions or documentary evidence alone, are entitled to some weight but not as great weight as when based upon conflicting oral testimony.

See:

Johnson v. Griffiths S. S. Co., 150 F. 2d 224-225 (9th Cir., 1945);

Matson Nav. Co. v. Pope & Talbot, Inc., 149 F. 2d 295, 298 (9th Cir., 1945).

The mere fact that the trial judge did not see any of the witnesses or hear them, does not mean that his findings are to be eliminated from consideration. Even in the case where the record depended upon depositions, it has been held that the findings cannot be disregarded and they will not be set aside unless clearly erroneous within the meaning of Rule 52(a), Federal Rules of Civil Procedure.

Heim v. Universal Pictures Co., Inc., et al., 154 F. 2d 480, 491 (2nd Cir., 1946).

A case quite in point is *U. S. v. Aluminum Co. of America*, 148 F. 2d 416, 433 (2nd Cir., 1945), where Judge Learned Hand pointed out that even where the trial court is to decide the case without hearing witnesses, his duty is to sift the evidence and put it in logical sequence and that it is "physically impossible for an appellate court to function at all without according some *prima facie* validity to his conclusions."

In the final analysis, Rule 52(a), Federal Rules of Civil Procedure, by the express terms thereof provides that "findings of fact shall not be set aside unless *clearly erroneous*." Certainly in this case the evidence was in sharp conflict and in addition thereto two of the principal Government witnesses were impeached to the point that not

much credence could be given to their testimony. Under these circumstances it hardly could be said that the findings of the trial court were clearly or otherwise erroneous and not supported by a preponderance of the evidence.

B. THE ACT IS NOT SUSCEPTIBLE OF AN INTERPRETATION THAT THE ADMINISTRATOR IS EMPOWERED TO DETERMINE WHAT DRUGS MAY BE SOLD ONLY ON PRESCRIPTION, IN WHICH EVENT NO DIRECTIONS FOR USE OR WARNINGS CAN BE "ADEQUATE."

1. PRELIMINARY STATEMENT.

On page 71 of the Government brief it is said that with "slight modifications the regulations authorized by 21 U. S. C., 352(f) have been in effect for ten years and have been respected by all reputable drug manufacturers and distributors. Only those who operate on and beyond the fringe of the law have sought to find loop-holes in the statute authorizing these regulations." On the contrary, there has been a great deal of dissension among drug manufacturers regarding these regulations and the Food and Drug Administration is at the present time revising them, especially those relating to the prescription clause, and have submitted to drug manufacturers as of now two proposed regulations for their comments with the view of them becoming permanent shortly.

To get an idea of the view of "reputable drug manufacturers" we refer the court to the November 1950 issue of the Food, Drug and Cosmetic Law Journal, Volume 1, No. 9, page 746. On this page appears an article entitled "Prescription Refills" by Walton M. Wheeler, Jr., Secretary and General Counsel of Eli Lilly and Company, one of the oldest and probably best known pharmaceutical manufacturers in the world. Mr. Wheeler in his

article discusses the Durham-Humphrey Bill, which will be found on page 79 of the Appendix to this brief. Mr. Wheeler discusses the very attempt of the Food and Drug Administration which is being made in this case to decide for itself what drugs may be sold on prescription, what drugs must be sold on prescription and therefore cannot be labeled with adequate directions for use or warnings. The author stated that soon following the effective date of the Act, became of dissension on the part of retail pharmacists concerning the prescription legend placed upon drugs by the manufacturers, the regulations under Section 502(f) of the Act were revised "so as to restrict the use of the prescription legends which could not be safely or effectively used without medical supervision" [R. 751]. He then pointed out that "the primary responsibility for selecting such drugs was left with the manufacturers, *since the Act conferred no authority upon the Food and Drug Administration to create classes of drugs or to specify the manner in which drugs of each class should be labeled and sold*" [R. 751]. He then went on to state as follows:

"But the implication and result of the regulations, when viewed in the light of the remaining subdivisions of Section 502, presented the problem of whether a drug which, in fact, is safe and efficacious only when used under medical supervision, may be labeled for over-the-counter sale without running afoul of Sections 502(a), 502(f) or 502(j). It appears that the view of the Food and Drug Administration is that the Act itself classifies drugs into counter items or prescription items on the basis of efficacy and safety following a factual determination on a case-by-case, product-by-product basis. If this be the proper interpretation of the Act (then obvious-

ly the law is basically a restrictive sales law; that is, it controls not only the manner in which a drug is labeled but the exact manner in which it must be sold. *Surely, if this be the proper interpretation of the Act, no one should be more surprised than Congress.* The battle for the enactment of the Act is portrayed in volumes of committee hearings, committee reports, and Congressional debates, and in countless early drafts of the Act. All of this material seems to support the conclusion that *Congress assumed and intended that a drug consumer would receive adequate protection if the label told him what he was taking, how to take it, and when to stop.* This is borne out by the oft-repeated quotation from the report of the Senate Committee on S. 5:

“The bill is not intended to restrict in any way the availability of drugs for self-medication. On the contrary, it is intended to make self-medication safer and more effective. For this purpose provisions are included . . . requiring that labels bear adequate directions for use and warnings against probable misuse. . . .’

“Accordingly, there is little to support the view that anything in the Act or in its legislative history requires drugs to be divided into two classes, the one class for distribution over the counter directly to consumers and the other class for distribution on prescription only. Therefore the present regulation which, by implication if not directly, requires the use of the prescription legend on drugs that may be used safely and effectively only under medical supervision is of questionable validity.” (Emphasis added.)

The proposed Durham-Humphrey Bill which is quoted in full in the Appendix seeks to give the Food and Drug Administration the very power which it now contends in

this case it already has. This bill is supported by the Food and Drug Administration and it would certainly appear that if the power already exists to decide what shall be sold on prescription and in no other manner, there would hardly be any need for such a bill.

Considering the language of Section 502(f) of the Act, 21 U. S. C., 352(f), the language in the proviso does not confer on the administrator the authority to decide which drugs may be sold upon prescription only but rather simply gives him the authority to exempt drugs from the requirement of adequate directions for use *when that requirement "is not necessary for the protection of the public health."* When it is necessary for the protection of the public health they shall be contained on the labeling, and when it is not necessary they may be exempted. This is a far cry, however, from an interpretation which would give the power contended for to the administrator. It is contended on page 43 of the Government brief that should this judgment be affirmed, then barbiturates, narcotics, etc., which have always been confined to prescription sales, could be sold without prescription. On the contrary, the Harrison Narcotic Act (26 U. S. C. A., Sec. 2554) requires the sale of narcotics on prescription. The sale of barbiturates is restricted to prescription in every state in the union. Penicillin and aureomycin can only be sold upon prescription for the reason that an amendment to the Food and Drug Act permitted the administrator to promulgate regulations certifying batches of these products before they might be sold and these regulations require prescriptions. In the final analysis there is no more danger as disclosed by the evidence in this case from the sale of these products labeled as they are labeled here, than there is in the sale of countless other products which are sold directly to the layman.

2. THE LEGISLATIVE HISTORY OF THE ACT IS CONVINCING THAT CONGRESS INTENDED LABELING OF DRUGS TO BEAR ADEQUATE DIRECTIONS FOR USE AND WARNINGS AND NOT TO EMPOWER THE ADMINISTRATOR TO DETERMINE THAT SOME DRUGS COULD NOT BE SO LABELED.

As pointed out in Mr. Wheeler's article, if the interpretation of this Act be that contended for by Appellants "no one should be more surprised than Congress."

At the Senate hearings on the original bill, S. 1944, W. G. Campbell, Commissioner of Food and Drugs, stated that the section was "merely to require that directions for use be stated on drug labels * * *. *It makes compulsory the use of a label*" [App. 63]. It should be noted that the original section [App. 62] as well as the section contained in the successor bill, S. 2000, both contained exemption provisions similar to that contained in the present Act [App. 63].

S. 2800 provided that the warnings on the labeling should be those prescribed by regulations [App. 64]. No such similar provision is contained in the present Act. The report in the Senate on S. 2800 stated that the paragraph involved required directions for use "*but where it is not necessary*" it could be exempted from that requirement. Note that there is nothing so far which would indicate that the members of Congress thought for a moment that they were to vest in the administrator the power to restrict the *manner* in which drugs might be sold; only that the labeling bear adequate directions, except that where this was not necessary for the protection of the public health they might be exempt from so doing. The same report [App. 64-65] stated that the mere giving of directions might not avert tragedy from likely misuse

“unless accompanied by positive warnings.” This is a fact and of course is true with numerous other drugs. Senator Copeland, the author of the bill, stated that it *“provides an effective safeguard against these dangers”*—dangers arising from lack of adequate warnings though the directions for use may be adequate [App. 65-66]. Mr. Campbell, in commenting upon this bill, attempted to allay criticism by pointing out that with the requirement of adequate directions for use and warnings, the public would be amply protected [App. 66] and, as Senator Copeland stated, in presenting that bill, it was not in any sense intended to do what certain objectors said about it: *“You can’t take an aspirin tablet without a doctor’s prescription.”* As to that he said, *“Nothing could be further from the truth”* [App. 66-67].

With reference to the succeeding bill, S. 5, the report in the Senate emphasized *“there are no useful products which would be barred from the market under this provision since labeling, with proper directions for use, would remove any worthwhile articles from this ban.”* It also stated that this provision was not intended to *“ban the sale of useful drugs when they are appropriately labeled”* [App. 67-68].

It would be presumed that if the committee had thought certain essential drugs might be characterized as so unsafe that proper labeling could not be devised for them, at that point it would have said so but instead it said the contrary.

It may be properly assumed that the requirement of Section 502(f)(2) of the Act (21 U. S. C. 352(f)(2)) requiring warnings against possible misuse, was regarded by Congress and the committee as sufficient protection of

consumers against misuse of the class of drugs which the Food and Drug Administration contends must, under regulation (Section 1.106) bear the prescription legend. There are repeated statements and committee reports and by sponsors of the several bills that the purpose of the section was to guard against misuse of "potent drugs" [See references, App. p. 68].

As pointed out on page 69 of the Appendix, some of the earlier bills leading to the enactment of the present Act provided that advertisements for certain named diseases "wherein self medication may be especially dangerous" should be deemed false except when disseminated to the medical profession. Note that there is no comparable provision in the existing Act. In other words, Congress rejected it and Senator Copeland stated in response to criticisms that under the Act a person would no longer be permitted to buy any "favorite prescription" and take it under the direction of the labeling, "Of course, that was not the intent of the proposed law" [App. 69].

Succeeding bills [App. 69-73] provided that labeling would be false unless it bore warnings as were required by regulation against use in certain conditions. These proposals, however, were rejected from the bill as finally enacted.

In the report in the House of S. 5 [App. 76], the same theme is carried on, that the bill was not intended in any way to restrict the availability of drugs for self medication but were intended to make it safer and more effective.

With regard to the warnings necessary, Senator Lea, one of the principal proponents of the bill, stated that a change had been agreed upon to require that warnings be "adequate" instead of those prescribed by regulation; but that the Secretary (the Administrator) can prescribe exemptions on the grounds of impracticability. It is evident here that there was no thought in the minds of the members of Congress that the Administrator was to do other than exempt drugs from the requirement of adequacy of warnings and directions when it was not necessary for the protection of the public health but that certainly he was not being vested with the power to decide what drugs could not bear adequate directions for use or warnings because in his opinion they should only be sold on prescription [App. 77]. Mr. Campbell's statements at the Senate hearings were to the same effect, that the labeling was intended to advise the consumer, and not one word was mentioned about the power now contended for being the intent of the Act [App. 78].

We do not believe that more need be said. We believe it plain from the legislative history that the intent was never entertained in Congress that the administrator should have the power now contended for by him. Instead of there being anything to indicate the grant of such power, all of the history is directly to the contrary and it is our firm conviction that in order for the contention of the Government to prevail it will be necessary to actually insert by judicial construction language into the section which cannot possibly be found there by any reasonable interpretation.

C. THE FINDINGS ARE FULLY SUPPORTED BY A PREPONDERANCE OF THE EVIDENCE.

1. PRELIMINARY STATEMENT.

The statements of Judge Westover at the time of announcing his decision are found in the record [pp. 960-965]. Among other things he stated that there was medical opinion on both sides as to whether taking this drug caused any ill effects but that the question rather was not what the effect of taking the drug was but what was on the packages [R. 963] and that he was doubtful under the circumstances whether any sort of labeling would meet the objections of the Food and Drug Administration; that in view of the admonition in four different places on the labeling to consult a doctor, "I don't know what more words would be put upon their cartons that would be a greater warning" [R. 965].

It should be kept in mind that the substance of the affidavits of Mr. Parkinson and Mr. Clemens are undenied by any counter-affidavits. In fact there is only one affidavit filed in response to Parkinson's affidavit and that is full of conclusions for the most part. The affidavits filed in response to the Clemens affidavit [R. 20, 120, 136] all go to the point that the revised labeling was not done in good faith and that persons who buy the product do not read the label.

The supplemental affidavit of Mr. Roe [R. 136] concerning interviews with persons who had purchased this product and that they did not read the labeling is of the rankest type of hearsay and wholly immaterial. If the right of a manufacturer to sell a product depended upon whether the individual to whom it was sold read the label, it could then be argued that any product was misbranded

in violation of the Act. Furthermore, carried to a further extreme, it might be questioned whether persons who obtained prescriptions read the instructions on the label and particularly might this be true where the prescription label simply states "take as directed."

In studying Appellant's brief, we find them stating in one breath that the labeling involved here is insufficient because it does not state all of the conditions of use and the warning statements are insufficient because technical words are employed, when in another breath they argue that *no* directions for use or *no* warnings can be adequate. It appears to us that this argument can simply mean that the Government is unsure of their position and are attempting to convince this court (1) that the directions and warnings are inadequate; (2) if the court should hold that the directions and warnings are adequate that nevertheless the product should not be sold except upon prescription. Obviously both of these contentions cannot prevail, for if the directions and warnings are adequate the statute is complied with and whether the Government is of the opinion that it should be sold upon prescription would be beside the point.

In Mr. Parkinson's affidavit [App. 47], he refers to an exchange of correspondence between Robert S. Roe, Chief of the Los Angeles District of the Food and Drug Administration and the Southern California Pharmaceutical Association, Ltd. In our opinion the letter from Mr. Roe is the antithesis of "clean hands," particularly when one considers that nothing was mentioned in his letter that the very question was before the court and knowing as he must have known that his letter to that organization would dissuade its members from purchasing this product. The Government is as much bound by the doctrine of

“clean hands” when seeking equitable relief as a private litigant. (*U. S. v. Belt*, 47 Fed. Supp. 239, 241 (1942) and cases cited therein.)

Throughout the Government's brief the tone is sounded (1) that the revision of the labeling following the criminal cases was not in good faith; (2) the assumption is made that the evidence established the contrary of that which the trial court found; (3) as though these consolidated cases were in fact the criminal cases which preceded them and which involved entirely different labeling; (4) that we acknowledge the danger of this drug and have attempted to do mere lip service to the requirements of the Act. At this point let us say that this revised labeling was composed following the criminal cases in an effort to comply with the theory and the evidence of the Government in the criminal cases. This was done without any admission on the part of the defendants that they agreed with the evidence of the Government witnesses. The revision was made, however, in good faith in an effort to avoid any further difficulties with the Food and Drug Administration.

The theories in the criminal cases and in these injunction cases were entirely different and so was the labeling. The trial court here was called upon to consider the evidence which had been introduced in the criminal cases, together with the additional record by way of affidavits as though that evidence were being introduced for the first time. No contention was made in the criminal cases that the Act provided that these products may only be sold on prescription, only that the labeling represented the product to be useful for many purposes for which it was not useful and that the labeling in the *Clemens* case should have had a warning statement and it did not. It should

be remembered that in the *Parkinson* case there was a warning statement and no charge was made that it was not sufficient. Several statements are made in the Government brief to the effect that these defendants are in the practice of promoting these drugs indiscriminately and for conditions for which they are useless, is a gratuitous statement for which no support in the record can be found.

In the footnote on page 30 of their brief, the Government quoted an editorial appearing in the *Pacific Drug Review* for the purpose of showing the alleged concern of others in the decision of the trial. This is a statement that is wholly improper and in direct violation of the rules to this court.¹

Throughout its brief, Appellant attempts to stress the so-called "dire consequences" that will result from the judgment in these cases because it is claimed that this drug is of such a character that no directions for use can be adequate. This of course flies in the face of the findings

¹In view of this quotation which we consider to be improper, we feel it only right that we should call to the attention of the court an article appearing on page 4, Part I of the *Los Angeles Times* of the issue of Friday, December 1, 1950. This article, written by one of the scientific editors of the *Los Angeles Times*, describes a meeting at the annual convention of urologists in Los Angeles. The conclusions of Dr. Robert L. Bacon of Stanford University were interpreted by Dr. A. J. Scholl, a member of the convention's Board of Governors. It was stated in the press article as follows: "Hundreds of men, it was brought out in the discussion which followed Dr. Bacon's talk, have feared to take the male hormone, testosterone, because of the fear that cancer of the prostate might develop. *There is not a single case in medical literature, it was revealed, in which the administration of testosterone brought on cancer.*" It was also stated in this article that "the strange new findings reported at the meeting is that *a few of the most advanced and virtually 'hopeless' cases of prostate cancer have responded amazingly, not to the female hormone but to testosterone, the male hormone. A few of these desperate cases actually recovered.*" (Emphasis added.)

of the trial court decided upon conflicting evidence. In support of those findings the following must be kept in mind:

1. To begin with there is nothing in the Act that gives the Food and Drug Administration the power to classify drugs into those for which directions for use can be written and those for which they cannot;

2. By reason of the conflicting character of the evidence and the impeachment of two of the principal Government witnesses, the trial court could and did find that nevertheless the directions for use were adequate.

In so doing, regardless of whether the Act gives the Food and Drug Administration the power to classify drugs, the court found that under the evidence the drug was not of such a character that the directions for use were not and could not be adequate because:

- (a) The Government and defense experts were in disagreement on the existence of a male climacteric and much of the scientific literature was in disagreement with the Government witnesses on the subject.

- (b) Likewise the Government and defense witnesses were in disagreement on the effect of the drug on fertility and likewise scientific writings were in disagreement with Government witnesses.

- (c) The Government witnesses themselves recognized a conflict to exist between their opinion and that of others.

- (d) Two Government witnesses, Dr. Belt and Dr. Heckel, were shown not to administer the elaborate tests which they testified were an absolute prerequisite to the administration of the drug.

(e) The associate of Dr. Belt—Dr. LeTourneau—gave a prescription for the drug without ever having seen the man for whom it was prescribed, let alone making any tests.

(f) A man 70 years of age (supposed to be the dangerous age so far as this drug is concerned) called at random on 15 general practitioners in the metropolitan area of Los Angeles, asked for a prescription of the drug and obtained it in each case without any of these doctors laying a hand upon him. Likewise many other general practitioners would do the same thing and likewise would testify in accordance with the testimony of the defense witnesses that such tests were not given, that the product was not dangerous, that the male climacteric was widespread and the drug was given for the relief of the symptoms thereof.

(g) The Government witnesses themselves were not uniform in their testimony as to the tests necessary to determine a hormone deficiency.

(h) The Government witnesses were professional and scientific investigators and experimenters and the methods employed by them in arriving at a conclusion were vastly different from those employed by the general practitioner who is the one to whom the individual goes for treatment or, as Dr. Belt put it, he is the “meat” for the general practitioner.

(i) That an individual would not receive the tests mentioned by the Government witnesses and therefore a label such as this one advising, among other things, to see a doctor, was more informative than if he obtained a prescription from a doctor who

gave no tests and on whose prescription the only directions were "take as directed" and with no warnings of any kind.

(j) That in the criminal case against Parkinson a warning statement was contained on his labeling which was apparently deemed sufficient as no charge was made in that case as to him that it was inadequate, or that no warning statement could be adequate.

(k) With respect to the charge that the 5 milligram dose has no therapeutic value, the United States Pharmacopoeia, the National Formulary, and New and non-Official Remedies, all standard medical publications suggest 5 milligrams as the dosage, and furthermore that Dr. Heckel, the Government witness, prescribed that dosage for Hazen Parkinson.

(l) That in the criminal actions certain counts involved 5 milligram products and no charge was made in either of those actions that 5 milligrams had no therapeutic value; that the old patent medicines, Dr. Pearce's Favorite Prescription, Dr. Pearce's Golden Medical Discovery, Dr. Miles Nervine, and Lydia E. Pinkham's Vegetable Compound, have been sold for many years with labeling which is subject to the same contentions raised by the Government herein and the fact that they have been and are sold under such labeling constitutes an administrative interpretation (See 42 Am. Jur., "Public Administrative Law", Sec. 78 *et seq.*) that the directions for use and warning statements on the labeling herein are adequate.

(m) That the labeling involved in *U. S. v. Hasenstein* [see R. 49], so far as directions for use and warnings are concerned is similar in many respects

to the labeling involved herein and that the District Court in the *Hassenstein* case found the label to bear adequate directions for use and warnings.

We have set forth in the Appendix to this brief, a narrative statement of the facts which we believe necessary to be reviewed in deciding whether those facts support the findings and conclusions of the trial court.

Finally, we are confronted with the astounding statement found on page 46 of Appellant's brief in which they state that this action "is a sort of *legal squeeze play* by the Government by which the Government hopes to eliminate worthless panaceas and dangerous drugs from indiscriminate distribution in the channels of commerce." This, in our opinion, constitutes an admission that nothing is to be found in the Act which supports the Government's theory that they are using a "squeeze play"—attempting to warp the interpretation of the Act to enable them to decide what drugs may and what may not be sold on prescription. If a "squeeze play" is valid here, then what is to prevent the Food and Drug Administration from at any time deciding that a certain drug shall be sold upon prescription only and instituting the remedies provided under the Act upon the theory of misbranding? How is a person to know in advance under such circumstances whether the product they are selling is one which the Food and Drug Administration has suddenly decided is dangerous and may only be sold on prescription? We seriously question the constitutionality of the Act under such an interpretation.

2. THE LABELING BEARS "ADEQUATE DIRECTIONS" FOR USE WITHIN THE MEANING OF 21 U. S. C. 352(f) (1).

We point out, to begin with, that the evidence of the Government on this phase of the case as contained in the transcript of testimony was on this point alone,—that methyl testosterone would be efficacious in the treatment of sweats, flushes, inability to concentrate on activities, etc., provided that they arose as a result of a male hormone deficiency but that no one but a doctor would be competent to determine that fact.

It is inconceivable how the directions for use could be more adequate than those contained on the label here, keeping in mind the testimony of the Government witnesses introduced in the criminal cases and found in the record here and the revisions made in precise conformance thereto. First, the individual is advised that the product is to be used by males deficient in male hormone when small dosages *are prescribed or recommended by a physician for the palliative relief of the symptoms of a hormone deficiency*. In order to eliminate any doubt on the subject, however, the label adds that it is impossible for an individual to determine whether he has a hormone deficiency and that therefore "*before taking testosterone a physician should be consulted*" as it will not aid or relieve symptoms not associated with a deficiency.

It is claimed that the labeling fails to state all of the conditions for which the product is prescribed, recommended or suggested in the labeling. It must be assumed that a proposed user of the product will heed advices such as mentioned. If they do, then the physician determines whether they are in need of it. If they do not, certainly the manufacturer or distributor cannot be charged with

mislabeling any more than could a manufacturer of iodine be charged with it if the user failed to heed the warning that it was poison, took it internally, was made violently ill, or died. As pointed out by Judge Westover, carried to the extreme which the Government would have it, no label for any drug, much less this one, could possibly be large enough to state all of the conditions which might be found in the medical textbooks *if* the Food and Drug Administration happen to decide that they do not want a particular drug sold except upon prescription and that therefore no directions could be adequate.

The Government claims that the suggested dosage contained on the label is intended to tell the user how to use the product without ever seeing a physician. This suggestion on the label is merely a suggestion which is found time and again on drugs sold directly to doctors. It is probably not necessary because it may be assumed, when the person has seen the doctor, that the latter has advised him how much to take. We know as a practical matter, however, that frequently the individual forgets the advice given by the doctor and more often than not the label on the prescription will say "take only as directed." Therefore in the event that the individual has forgotten or the doctor has failed to advise him how much to take, this suggestion is given to him and no contention is made that it is incorrect. After all, it is merely a "suggestion", not to be followed if the doctor directs otherwise. Under the heading "suggested dosage" the individual is further cautioned that merely because the doctor has recommended the product, he should not keep on using it for an unlimited period of time and in fact should not use it as long as three months unless he does so under the supervision of a physician.

Throughout the Government's brief the claim is made that the defendants simply do "lip service" in compliance with the Act. Hardly can such a contention validly be made after the critical review of the evidence given by Judge Westover and his conclusion that the Act was not violated. On the subject of the labeling bearing a statement of all of the conditions and diseases for which the drug is contended, let us consider a small practical example aside from anything else. If this contention were true, it would mean that a drug, for example, a laxative sold as a laxative for constipation, would have to carry on the label adequate directions for every symptom of constipation that might exist. For instance, constipation can cause a temporary dull headache, bloating, abdominal discomfort, dullness, lack of energy, and these symptoms might be enumerated *ad infinitum*. To list all of those symptoms on the label would not only be wholly impracticable but would present an impossible labeling problem.

Alberty Food Products Co. v. U. S. (9th Circuit, November 20, 1950, No. 12,483) is cited on page 41 of the Government brief. This case is no authority at all for the reason that the label there failed to indicate any purpose whatever for the use of the product.

In conclusion under this point, we submit, as found by Judge Westover, that if the requirement that adequate directions for use appear on the labeling means anything at all, it certainly has been complied with on this labeling.

3. THE LABELING BEARS "ADEQUATE WARNINGS" WITHIN THE MEANING OF 21 U. S. C. 352 (f) (2).

The claim is made here in one breath that the warning language on the labeling is couched in technical terminology which the layman cannot understand. In another breath it is stated that no warnings can be adequate and therefore the product may only be sold on prescription. One of these principles must be true, not both.

We again remind the court that in the *Parkinson* criminal case a warning statement was contained on the labeling which must have been deemed sufficient for no charge was made there that the language was inadequate. Mr. Parkinson revised his labeling so as to conform to the evidence introduced by the Government in the criminal cases, not, however, in the belief that they were correct in their position and certainly he was fortified in this belief by the impeachment evidence of Drs. Belt and Heckel.

On page 34 of the Government brief it is stated that a temporary restraining order was not sought against Parkinson because he was selling a product of a lower potency—5 and 10 milligrams. We wonder if by this the Government means that this potency would not cause cancer as much or as quickly as a higher potency. If so, where is the dividing line? There is certainly no evidence in the record to support such a contention.

On page 24 of the Government's brief it is argued that the product is not saved from being "dangerous to health" by reason of the suggestion in the labeling that a physician be consulted prior to its use. However, the Food and Drug Administration, in their published list of accepted

warnings for over-the-counter products, suggests the following warning for atropine:

“WARNING: This preparation should not be taken by elderly people except on competent advice.”

The reason is that an elderly person taking atropine can be seriously injured. Therefore atropine is a dangerous drug but the Food and Drug Administration must feel that it is safe from being dangerous by a suggestion such as stated. In fact the same is true with most drugs; if taken under certain circumstances they may cause serious illness or death. Aspirin can have serious effects if taken in excessive quantities. Bromides the same. Yet we find Bromo Seltzer sold at nearly every soda fountain. Dr. Thienes, a Government witness, stated that people go to mental hospitals from over-doses of bromides and that an excess of bromides can cause mental derangement [R. 382-383]; also that people taking an excess of Alka Seltzer will, in the long run, find themselves suffering from alkalosis; and that is sold over the counter [R. 383].

Mr. Roe of the Food and Drug Administration filed an affidavit [R. 136] alleging investigations made by his office to determine whether people who bought these products paid any attention to the labeling and regardless of the admissibility of the affidavit the effect was that a majority did not. If this product causes all of the harm that the Government would have this court believe, it certainly would seem that they would have produced an affidavit from someone who had been harmed by the taking of it but not one was offered, nor, as a matter of fact, was any offered to show that people who had taken the product had failed to obtain the results advertised for them.

Why is it that the Government assumes, in this case, that the individual is unable to heed the warning state-

ment? In other cases the Government presumes the layman capable of at least finding out whether he has the condition warned against. For instance, the accepted warnings for bromides is that they shall "not be taken by those suffering from kidney diseases." This warning doesn't even suggest that the layman go to a physician and find out whether he has such a disease.

On page 34 of the Government brief it is said that the revised labeling involved here acknowledges the restricted usefulness of the drug as well as their dangers. As we have said, this labeling was devised to meet the objections made by the Government during the course of the criminal cases. Certainly there is nothing wrong with labeling that does just that, for the same is true with many other drugs sold over the counter. We have already mentioned bromides. Acetanilide is sold with a warning statement that frequent or continued use may be dangerous, causing serious blood disturbances, anæmia, etc. In view of all of that, what is there in the evidence to require the court to find that the warning statement on the labeling here is not and cannot be adequate?

On page 49 of the Government brief it is stated that "With an established clientele and a crystallized concept in the public mind," it is not necessary for the defendants "to be as outspoken as heretofore in hawking their wares." If this drug is all that it is claimed to be, dangerous to health and of no value, there could hardly be an established clientele for they would either have all died or stopped using the product one way or the other, maybe both.

When we consider what this labeling advises and what the Food and Drug Administration permits in other cases of a comparable character, we begin to understand the

significance of the “squeeze play” mentioned on page 46 of the Government brief. That play is nothing more or less than an attempt to “squeeze” these defendants out of business simply because the Food and Drug Administration has concluded, without any statutory authority, that the product should be sold only on prescription notwithstanding the conflicting evidence and the conclusive impeachment of Drs. Belt and Heckel and the findings and conclusions of the trial court based upon that evidence.

With regard to the so-called technical terminology employed in the warning statement, the same type of terminology was employed in the *Hassenstein* case [R. 49] and held to be sufficient and the same objections were made in that case as made here.

Note particularly that the term “carcinoma” was the language employed in the informations in the criminal cases. It must be assumed that in using that language the Government intended to comply with Rule 7(c), Rules of Criminal Procedure, and considered that term to be a “plain, concise and definite” statement of fact constituting an element of the offense charged. Here again the Government says in one breath that the warning statement is inadequate because of technical language used and in another breath states that no warning language can be adequate. Paraphrasing the language of the court in the *Hassenstein* case, the terms “carcinoma” and “spermatogenesis” are dictionary words which are clearly understood to mean, respectively, cancer and the ability to produce offspring.

In view of the contention made that this product is inherently dangerous and should only be sold on prescription, it follows that contention presupposes that if a person should call on a doctor he will conduct elaborate tests to determine whether there could be any potential danger in

taking the product. However, we have the testimony of Hazen Parkinson who called on 15 different doctors in general practice in Los Angeles and Long Beach and obtained a prescription without any of them laying a hand on him. That reflects the attitude of the general practitioner who, Dr. Belt admits, was the one to whom an individual would go—was his “meat.” It certainly may be assumed that if such was the case, with 15 doctors picked at random, the same would be true with the vast majority; the same as in sampling a product containing many packages, one may assume that several samples picked at random from the container are demonstrative of the condition of the whole. Therefore a prescription under these circumstances would mean far less than the informative labeling which is before this court.

4. THE DRUG IS NOT DANGEROUS TO HEALTH WITHIN THE MEANING OF SECTION 21 U. S. C. 352(j).

What we have heretofore said under subheading 3 is applicable here as well, that is, that the drug is not dangerous to health when used in the dosage and with the frequency or duration prescribed, recommended and suggested in the labeling and that was what Judge Westover found to be the case on the record before him.

5. THE LABELING IS NOT FALSE AND MISLEADING WITHIN THE MEANING OF 21 U. S. C. 352(a).

The charge is made that the 5 milligram dosage is therapeutically worthless and therefore the labeling of such a product is false or misleading.

It is conceded by the official United States Pharmacopoeia and other authorities that the sublingual dose of

5 milligrams is equivalent to the oral dose by mouth of 10 milligrams. Dr. Huggins testified that a male hormone deficiency in his institution is treated by 10 milligrams by mouth [R. 546] which, as we say, is the equivalent of 5 milligrams sublingually, which in turn is the dosage involved here. On the other hand, we have Dr. Belt, a Government witness, stating that 5 milligrams sublingually is worthless [R. 17]. When confronted with the recommended dosage found in the United States Pharmacopoeia and the National Formulary, the Government contends that the United States Pharmacopoeia may be out of step. If this sort of an argument is worth anything, then these two nationally accepted publications might as well be forgotten and reliance upon them in the Act eliminated. Nevertheless the new United States Pharmacopoeia has appeared since all of the testimony in this case. The 14th edition became effective November 1, 1950, and on pages 366-368 the dosage for methyl testosterone is given and reads as follows:

“Usual dosage of methyl testosterone, 10 milligrams, sublingual 5 milligrams.”

Also, as pointed out, Dr. Heckel, the Government witness, wrote a prescription for 5 milligrams for Mr. Hazen Parkinson [R. 901].

Also in the criminal information 5 milligram tablets were involved and no charge was made that they were therapeutically worthless.

V.

CONCLUSION.

Much of what is said in the Government's brief is matter entirely extraneous to the record. The fact remains that these products were relabeled so as to conform precisely to the contentions made and the theory advanced by the Government in the criminal cases. It is sought here for the first time to interpret Section 502(f) (21 U. S. C. 352(f)), in a manner never done before and which power is sought to be given the Food and Drug Administration by the Durham-Humphrey Bill. The power now claimed, we earnestly contend, is not given to the administration by any reasonable interpretation of the Food and Drug Act. The trial court found upon conflicting and convincing evidence that there was a conflict of opinion as to the danger contended for and that the directions for use and warnings were adequate. We submit that these findings under the evidence are far from being "clearly erroneous" within the meaning of Rule 52(a) of the Rules of Civil Procedure, but are simply supported by a preponderance of the evidence and that the judgments must therefore be affirmed.

Respectfully submitted,

EUGENE M. ELSON,

Attorney for Appellees.

APPENDIX.

I.

THE PLEADINGS IN CASE NO. 10266-HW (THE EL-O-PATHIC OR CLEMENS CASE).

1. THE COMPLAINT AND AMENDMENT TO COMPLAINT.

The complaint alleged that the defendants distributed methyl testosterone tablets 10 mgs. and 25 mgs., and in linquet form 5 and 10 mgs. and various preparations of female hormone drugs [R. 3]; that they were purchased from three different companies and as received from the manufacturers the label bore the legend "Caution: To be dispensed only by or on the prescription of a physician." [R. 3]; that in the sale of these drugs a physician's prescription was not required by defendants but that they re-packaged and relabeled them for sale without a prescription. For example, the linguets were labelled as follows [R. 4-5]:

"El-O-Pathic Hormones

50 Tablets

Each Tablet Contains

10 Mg. Methyl Testosterone

"Suggested Dosage: One Tablet upon arising before breakfast or one tablet shortly before retiring. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from three to six months, under supervision of a physician.

“Directions: For use by adult males deficient in male hormone (3) when small dosages of male hormone are prescribed or recommended by a physician for palliative relief of such symptoms.

Distributed by El-O-Pathic Pharmacy
1109½ No. Western Ave. Hollywood 27, Calif.
Hollywood 9-1722
(Read Side Panels)
(Side Panels)

“Caution: The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate or by anyone with cardiovascular disease, defects of spermatogenesis, sterility whether absolute or partial, or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed.

“It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted, since testosterone will not aid or relieve symptoms not associated with male hormone deficiency. Children and young adults must not use except under constant direct supervision of a physician.”

That in displays and newspaper advertising defendants suggested said drugs to be efficacious in alleviating disease conditions, particularly those relating to sexual impotence in men and change of life in women [R. 5]; that defendants violated Section 301(k) of the Act (21 U. S. C. 331(k)) in that the printed matter constituting labeling fails to bear adequate directions for use in failing to state all of the diseases or conditions for which the drug is in-

tended and that they violate Section 502(f)(2) of the Act (21 U. S. C. 352(f)(2)) because the labeling fails to bear adequate warnings against use in pathological conditions where its use may be dangerous to health in such manner and form as are necessary for the protection of the user, as the medical terminology constituting the cautionary statement is not adequate to warn the ordinary user that its use may accelerate a growth of cancer of the prostate or cause sterility; also that Section 502(j) of the Act is violated (21 U. S. C. 352(j)) in that the linguets are dangerous to health when used in the dosage and with the frequency prescribed as the drug may result in sterility and may accelerate the growth of cancer of the prostate [R. 5-6]. It was also alleged that Section 301(a) of the Act (21 U. S. C. 331(a)) is violated in the shipment of 10 mg. linguets misbranded in the same particulars [R. 6].

With respect to the 5 mg. linguets labeled as aforesaid, it was alleged that Section 301(k) of the Act (21 U. S. C. 331(k)) was violated because one tablet daily would be ineffective for the treatment of a male hormone deficiency, that the labeling failed to bear adequate directions for use and adequate warnings in the particulars as mentioned [R. 7-8]; that Section 301(a) of the Act (21 U. S. C. 331(a)), was violated because the 5 mg. linguets were misbranded in particulars aforementioned. It was alleged with respect to the tablets that "it is likely that the defendants will cause the same violations" of Sections 301(a) and (k) of the Act as they are causing with respect to the linguets as the defendants have in the past sold the products frequently without a physician's prescription and without adequate warnings [R. 8]. The conviction in the criminal action No. 20596—Criminal, on July 13, 1949,

was alleged and that within a month after the convictions the defendants embarked upon a wide spread promotion of the same products in essentially the same misbranded condition and that the revision of the labeling is a subterfuge by which the defendants hope to deceive the court and defraud the public [R. 9].

A temporary restraining order was applied for and an injunction to restrain defendants from in substance introducing into interstate commerce the drugs mentioned, in a misbranded condition [R. 10-11].

2. THE ANSWER.

The answer of the defendants in this case, in substance denied all of the material allegations of the Complaint. There was attached to the Answer as Exhibit "A," the labeling employed [R. 35-44].

II.

THE PLEADINGS IN CASE NO 10391-HW (THE HUDSON PRODUCTS CO. OR PARKINSON CASE).

1. THE COMPLAINT.

The complaint in this action was essentially the same as in action No. 1266-HW [R. 162-174], except the product involved was 5 mg. and 10 mg. However, no temporary restraining order was applied for.

2. THE ANSWER.

The answer in this case in substance denied the allegations of the complaint [R. 179-186] and specifically denied any intention to sell the female hormone drugs referred to in the complaint or that any had been sold by them since July 13, 1949, the date of the conviction in the criminal action.

III.

EXCERPTS FROM THE EVIDENCE.

The evidence in these consolidated injunction cases, by stipulation consisted of the pleadings and affidavits and the transcript of proceedings in the consolidated criminal cases *United States v. El-O-Pathic Pharmacy, et al.*, No. 20,596—Criminal, and *United States v. Parkinson*, No. 20,642—Criminal [R. 150; 269].

Any reference to the female hormone will be eliminated herefrom for the reason that it was never an issue in the trial court [R. 156, 272].

1. EVIDENCE OFFERED IN SUPPORT OF THE COMPLAINTS.

(a) Affidavits of Doctors Thienes and Belt.

Drs. Thienes and Belt filed affidavits in support of the application for a temporary restraining order and preliminary injunction in action No. 10266-HW, in which they each represented in part what was testified to by them previously in the criminal actions which testimony is part of the record here. In addition, however, they stated that these drugs should not be sold except upon prescription [R. 12-17].

(b) Affidavit of Robert S. Roe.

Robert S. Roe, Chief of the Los Angeles District of the Food and Drug Administration executed an affidavit in support of the application for temporary restraining order and preliminary injunction in case No. 10266-HW, to which was attached a letter introduced in the criminal

action and dated July, 1947. This letter was from Roche-Organon, Inc., and according to the affidavit was sent to defendant in that action and other distributors. The affidavit concludes that it "indicates defendants were warned two years ago as to the dangers inherent in the indiscriminate sale of these drugs to the public without a physician's prescription" and that defendants are now unloading a large quantity of these drugs without prescription upon the public [R. 20-22].

Under the stipulation as to the record in action No. 10266-HW [R. 150], the supplemental affidavit of Robert S. Roe, concerning the investigations made by his office as to whether purchasers of the product consulted physicians before using it [Appendix, p. 58; R. 136]; the affidavit of Wells [Appendix, p. 58; R. 131-136]; the affidavit of McRae [Appendix, p. 59; R. 107-118], and the transcript of the evidence, including exhibits, in the criminal cases, were made part of the record in this injunction action, subject to any objections as to relevancy and materiality.

In the action against Hudson Products Company, No. 10391-HW, the aforesaid supplemental affidavit of Roe, the affidavit of McRae, and the transcript of the evidence, including exhibits in the criminal cases, were made part of the record subject to objections as to relevancy and materiality. However, it was further stipulated in this action that none of the evidence in the transcript of testimony pertaining to the alleged danger of using testosterone under certain circumstances, was introduced as against

Allen H. Parkinson, defendant in No. 20642—criminal, and there was no charge by the government in that action that the warning statement on the labeling which related to the product sold by him was inadequate [R. 266].

As will be pointed out in the affidavits of Clemens [R. 49] and Parkinson [R. 53; pp. 42 and 47 of this appendix] following the judgments of conviction in the criminal cases they completely revised the labeling to conform to the objections made by the Government in those cases as reflected by the testimony of Government witnesses, even though their medical witnesses disagreed therewith. That labeling as revised presents the questions that were before the trial court in this litigation and before this court on this appeal, namely, whether the labeling involved *here* contains adequate directions for use and adequate warnings.

Suffice it to say that all of the witnesses for the Government in the criminal cases testified substantially that the male hormone was of great benefit to persons suffering from a male hormone deficiency, but that an individual was incapable of diagnosing that condition and that there was danger in taking the product without consulting a physician first in that it may accelerate the growth of a carcinoma of the prostate and might cause partial loss of fertility.

The Appellant's brief, pages 2 to 8, sets forth the references to the transcript of testimony in the criminal cases in which the opinions of these witnesses on those subjects appear.

(c) Testimony of Dr. Clinton A. Thienes.

On the basis of his education and experience he thinks he knows the consensus of medical opinion regarding the toxic effects which methyl testosterone may have upon the adult male [R. 353]. That consensus is that such product may produce a condition which would result in a deficiency in the ability to reproduce. His opinion is the same as the consensus [R. 354-355]. Assuming a man to be suffering from flushes, sweats; is extremely nervous, unable to concentrate and is suffering from nocturia, and he called on an average general practitioner, other things being equal he cannot say that such a practitioner would, under the circumstances, prescribe testosterones for a period of time and wait to see whether the symptoms were relieved as he the witness would have to know of what the practitioner's examination had consisted and what the urologist may have done in the way of examination [R. 365]. Even if the urologist's report was that he had palpated the prostate and performed a biopsy and there was no evidence of cancer of the prostate and no enlargement; that laboratory tests were conducted with nothing to indicate any presence of such a cancer, that would not be adequate to determine whether testosterone should be administered for those symptoms as there would have to be proof that there was a marked decrease in the secretion of testosterone [R. 365-366]. Whether such a complete examination is made in every case that an individual is sent to a urologist under such circumstances would depend on what the urologist was asked, but he thinks that most competent urologists would

return the patient with advice to the general physician and before arriving at a conclusion as to what advice he would give he would certainly determine whether there was evidence of a male climacteric and that would involve determination of the secretion of male hormone [R. 366] and so it would only be then if a man was actually suffering from a deficiency of the male hormone as determined by the amount of secretion of the male hormone and after a urologist diagnosed that no cancer of the prostate was present and the laboratory tests referred to have been taken not indicating the presence of such a cancer that he thinks the doctor would give testosterone [R. 366-367]. He thinks today that the general practitioner would want to know for sure whether the man was suffering from a case of climacteric before giving testosterone even after receiving a report from the urologist there there was no presence of cancer of the prostate [R. 367]. There is no such thing as the average general practitioner [R. 367]. He thinks that the majority of general practitioners would require a laboratory test prior to prescribing it and that thought is based upon his knowledge of medical literature. Testosterone has been responsible for prostate cancer growing rapidly but he would not say that it caused a cancer to develop or actually start [R. 368]. He doesn't remember any specific instance at the moment where such a fact has been proved clinically [R. 369]. He cannot state what literature he had reference to that led him to interpret the literature to indicate that testosterone will accelerate the growth of cancer of the prostate [R. 369].

The only way to determine whether a person is suffering from a hormone deficiency is to make laboratory tests [R. 386]. These tests consist of sampling the urine [R. 392].

(d) Testimony of Dr. Warren Nelson.

His studies have been conducted at the University and have concerned humans as well as experimental animals. In the case of humans the procedure is to obtain a sample or biopsy of both testes prior to treatment, administer the hormone for a period of time, at the end of which a second biopsy would be obtained and compared with the first [R. 396-397]. His studies have shown to him that the administration of testosterone decreases the activity of the testes in the production of spermatozoa and in the production of testosterone in the testes. This decrease would last for the duration of the treatment. How much beyond that it is difficult to say [R. 396-398]. He went into considerable technical detail to explain the reasons for his conclusion and stated that in general such information and details are included in his teaching to medical students, though he has more occasion to discuss those matters with medical societies and groups in various parts of the country [R. 400-401]. In the case of eunuchoids, testosterone has been administered in the majority of cases but in some instances incorrectly because the case was not properly diagnosed [R. 407-408]. From his own research he was unable to make any statement as to the effect of the administration of methyl testosterone on the testes [R. 413]. The only way in which it could be determined

whether there had been any damage to the testes which in turn would tend to decrease fertility, would be an examination of a sample of the testes by microscopic examination [R. 414]. He said that the practice of taking a sample of the testes and examining them in that fashion was done very, very widely now and was a widely recognized procedure [R. 415]. When he stated that it was his opinion that methyl testosterone inhibits sperm production he meant that it was his opinion that that was the consensus of opinion [R. 415-416]. He is sure that any doctor who prescribed testosterone would warn the individual of the possibility that his fertility would be decreased and he thinks that that would be the practice of the general average practitioner in dealing with a person who the doctor found was suffering from symptoms associated with the male climacteric [R. 422]. It is undoubtedly a procedure that is done in some instances to administer testosterone to a person who manifests the symptoms associated with the male climacteric, and to assume that if, after taking testosterone, those symptoms are relieved, the man was going through the male climacteric. However, at the University, laboratory tests are made to determine whether he belongs in that category or should receive some other form of therapy [R. 428]. It is inevitably true that there is a difference between the method employed by a scientist such as the witness conducting his work in a university, or in experimental institutions, and the method employed by the average general practitioner. The factors of time, economic factors and many others enter into [R. 424].

(c) Testimony of Dr. Norris J. Heckel.

He is a urologist and professor of urology at the University of Chicago [R. 464]. In urology he uses testosterone only for the treatment of men who have a deficiency of the male sex hormone. The best illustration of such deficiency would be eunuchism, a disease in which the body has not been able to manufacture the hormone and consequently the individual has not developed as the normal male [R. 465]. Other types of persons who have a male hormone deficiency are those whose testes have been destroyed from some disease or who have been castrated [R. 466]. Hormone therapy would not correct impotence in a man in his late 40's unless it was due to a male hormone deficiency [R. 471]. If a man were suffering from a male hormone deficiency methyl testosterone would correct lack of sexual power and impotence, would postpone the many conditions associated with middle age and improve the sense of well being and would constitute an adequate treatment for flushes, sweats and chills, impaired memory, inability to concentrate on activities and a tendency to evade them, nervousness, depression, general weakness and lack of physical strength [R. 472-474]. There are many diseases other than such a deficiency that would produce those symptoms. If a man were suffering from such a deficiency methyl testosterone would result in impowered physical and mental work and would exert a tonic action resulting in renewed vigor and would impart a better attitude towards social life and cause nervousness, exhaustion and melancholy to disappear. Each of those symptoms are also symptoms of conditions other than a male hormone deficiency [R. 473-475]. A male hormone deficiency is determined (1) by a case history, (2) a careful physical examination and (3) laboratory tests to aid in the diagnosis such as the estimation of 17

ketosteroids in the urine and also by the estimation of the secretion of gonadotropins in the urine. There are no objective symptoms which would enable him to correctly diagnose a male hormone deficiency [R. 475-476]. In his opinion methyl testosterone will aggravate the growth of a prostatic cancer [R. 478-479].

On cross-examination he stated that if a patient called upon a general practitioner complaining of the several symptoms enumerated in his opinion the doctor would make a careful examination of the patient to see if he could find out the cause of the symptoms. He would conduct a complete physical examination from head to foot. If that produced nothing he would examine the urine to see whether there was any sugar in it which might give him a clue to diabetes which would produce such symptoms. If he found no sugar he would determine whether there was any albumin in the urine or whether the patient was suffering from Bright's disease or some kidney disturbance and an X-ray picture of the tract or the colon tract or a basal metabolic test to discover whether he had some disturbance of the thyroid. If the general practitioner found nothing suspicious as a result of that examination *he might but he shouldn't* suggest testosterone to the patient for a period of 4 to 6 weeks to see if those symptoms were relieved. He really doubts that the general practitioner would suggest testosterone for a period of time after the result mentioned of such an examination [R. 482-486].

He has never been able to make a diagnosis of the male climacteric. He knows that it is spoken of in the literature as a condition something comparable but not the same as the female menopause [R. 487]. It is frequently referred to in laymen's magazines and medical publications. There is no question about it at all that in view of the hundreds

of thousands of packages of methyl testosterone sold in the aggregate by the three principal manufacturers during the period of a year the product is indicative of considerable benefit to many, many men [R. 489]. From his own experience he believes that methyl testosterone accelerates the growth of a cancer of the prostate [R. 491]. He doesn't think that testosterone in any form causes prostatic cancer [R. 492]. The whole prostatic cancer problem and its relation to hormones is a relatively new thing [R. 493].

There are no blood tests or urine tests to determine the presence of cancer [R. 503-504]. He does not agree that the average general practitioner or family doctor who found what he believed to be a male hormone deficiency and who examined the patient to see whether cancer was present and found none, would try the man on testosterone to see whether he was relieved of the symptoms. The chances the 99 times out of 100 that he would find some specific reason for the man's symptoms [R. 506-507]. The large pharmaceutical concerns such as Ciba, Schering and Roche-Organon, who are the principal manufacturers of testosterone, send out lots of literature, maintain large research staffs and the information which they supply the doctors with in general is abreast of the times though he disagrees with some of it [R. 509-510]. He agrees with the statements reported to have been made by Dr. Hans Lissner and Dr. Robert Escamillo reported in "The Urology and Cutaneous Review," Volume 46, page 87 (1944), with respect to the effect of testosterone on the testes, and reading as follows:

"On the other hand, there have been reported patients whose sperm counts increased after treatment to the extent that successful impregnation took place. Other authors have pointed out that both number

and viability of the spermatozoa can fluctuate during the continued use of androgens, or that the count is 'of minor significance as compared to the enormous improvement obtained in all other respects.' "

(f) Testimony of Dr. Elmer Belt.

Is a urologist [R. 515] and member of the Belt Urological Group [R. 516], a member of several scientific societies and has written several articles on medical and scientific matters [R. 516]. He thinks he has personally seen or treated patients who have had adverse results from the administration of the male hormone [R. 517]. He gave an example of a patient under his care who is suffering from cancer of the prostate and he thinks that the administration of testasterones which this person took very likely, very definitely influenced the growth of that cancer. The patient, incidentally, is a doctor of medicine. Cancer of the prostate is frequent in the decade between 50 and 60 and is much more frequent between 60 and 70 [R. 519-520]. In the case of the ordinary practitioner to whom a patient goes because he wants a general physical examination, the practitioner is obligated to place his finger in the rectum and carefully feel the prostate [R. 522-523]. There are many more things to know about cancer of the prostate than are known about it [R. 532]. He thinks that methyl testosterone is dangerous in that it could aggravate a cancer of the prostate [R. 533]. There are many instances in which methyl testosterone is very valuable. The precautions necessary prior to its use are tests, rectal examinations, the level of acid phosphatases in the blood stream, and two other tests of very recent origin, comprising a test of proteins of the blood and a blood protein test. These tests are a prerequisite except in groups where cancer of the prostate is not liable to

occur and by that he means cases in which it is particularly valuable or the groups of young individuals who show a definite endocrine deficiency in regard to testosterone and who need it in the normal process of their growth and development [R. 535]. He is referring to boys who had their testicles blown off in the war and persons suffering from hypogonadism, persons whose testicles are not performing their proper function, meaning undeveloped testicles and undeveloped genitalia, a young individual whose testicles are not up to standard in size and in function [R. 655, 656]. The acid phosphates test is one which can be completed in a few minutes if one is set up for it. The 17 ketosteroids requires approximately a week to complete and the blood test a very short time. The general practitioner is not equipped to make either of those tests and in fact his office is not equipped to make the 17 ketosteroids test and he is having them made at the California Institute of Technology [R. 659]. In a person who is apparently normal physically, the examination necessary to determine whether he is suffering from an endocrine deficiency might possibly be the 17 ketosteroids test [R. 536]. The examinations he has referred to require special training. There are no objective symptoms of a male hormone deficiency which a layman could recognize and use to diagnose such a condition [R. 537]. After a careful examination of the patient and no indications of cancer of the prostate being present, *it would still be dangerous and conducive to the development of cancer of the prostate for the person to take testosterone* [R. 538-540]. In his opinion if a man 40 to 50 years of age called on a general practitioner and stated that he was troubled with sweats, nervousness, did not remember things as he used to, couldn't concentrate on activities and had a tendency to

evade them, and the doctor was of the opinion after learning of these symptoms that testosterone might be of benefit to the patient, the general practitioner would, before prescribing it in the first place think—think about the problem and if he thought about it very much he probably wouldn't prescribe testosterone for those symptoms, because they do not indicate hypogonadism and it is virtually only in hypogonadism that testosterone is effective [R. 648-649]. A very careful analysis of the problem would be made for that patient and he would be very apt to get it at the hands of an alert general practitioner [R. 650]. It would be a very loose method of detecting the man's trouble for the general practitioner to prescribe testosterone to the patient for a period of 3 to 4 weeks to see whether the man had been relieved and if the doctor really thought about the problem, got down to business and studied it, he would be concerned first about the psychic features in the individual and whether he was overworked and troubled. Before prescribing testosterone the general practitioner would certainly make a rectal examination. *There would be no blood tests which such a doctor need do unless he wishes to do the acid and alkaline phosphatase test. The urine test would not show him anything unless he wished to take the time to give the 17 ketosteriod tests* [R. 650-651]. *If he really wanted to find out whether the man had a hormone deficiency he would give such a test, as well as the acid phosphatase test for cancer of the prostate and if he used testosterone then he would say that the symptoms were not relieved* [R. 651-652].

The problem of hormone deficiency is the specialty of the general practitioner. The middle age man who is tired and worn out and who has come to the doctor for some help is the general practitioner's "meat" [R. 653].

In the case of the individual who comes to the general practitioner, who gives him a rectal examination and finds nothing suspicious and prescribes methyl testosterone for him and the prescription given him is filled, that patient may return to a drug store as often as he wishes and have it refilled without going to the doctor or any other doctor and obtaining a new prescription everytime he wants it. He can go back and have it refilled as often as he wants without ever seeing another doctor [R. 662-663].

He does not think that the male has any climacteric and he believes most careful observers are of the same opinion. This opinion, however, is not universally shared by the profession [R. 669].

(g) Testimony of Dr. Chas. Huggins.

Professor of Urology, University of Chicago; holds several degrees and is a member of several societies and has written many papers on urological and scientific subjects. Since 1938 his practice has been almost exclusively related to the male hormone and its action in normal and cancerous individuals [R. 540-542]. He does not believe that a male hormone deficiency occurs in quasi-normal individuals—people who are not hypogonads or who have not been castrated. Testosterone accelerates the growth of cancer of the prostate [R. 562, 566-567]. As to the blood tests to determine the presence of cancer of the prostate, the ordinary general practitioner is not capable of conducting such tests unless he is chemically minded, but the average, good-sized hospital can determine it [R. 569-571].

The blood test he referred to can only be done in well established hospitals. He does not believe that there is

such a thing as the male climacteric, though there is a difference of opinion on that subject in medical circles and there are a great many articles in which the male climacteric is discussed but he does not share the opinion of those investigators [R. 581-582]. He, the witness, is a professional investigator [R. 588]. Eliminating eunochoids castrates and women, he does not think they have been prescribed in his hospital—University of Chicago—for the last 5 years. *He disagrees* with the statements concerning the male climacteric by Drs. Hans Lisser and Robert F. Escamilla appearing in Volume 46 "The Urologic and Cutaneous Review," page 87, February, 1942, entitled "Testosterone Compounds in the Male. Clinical Indications and Methods of Administration," under the heading "Male Menopause" and reading as follows [R. 589]:

"Until recently the male menopause has been ignored except for rather bizarre attempts at rejuvenation by testicular graftings or by tying the spermatic cord (Stenach's operation). Perhaps this neglect was due to the conception that the male menopause consisted merely of the natural diminution and final loss of libido and potency in advancing years. Little heed was given to the less obvious but more important manifestations consisting of mild vasomotor flushes, increasing irritability, failing memory and decreased capacity for mental effort. The customary day's work is not accomplished as speedily, as cheerfully or as effectively as before. We are inclined to believe that during this period conservative androgen therapy is indicated and may be highly beneficial. However, care must be exercised to avoid undue sexual stimu-

lation, especially in men (314) between 50 and 70 years of age who suffer from hypertension or show evidence of arteriosclerosis or myocardial damage.”

He disagrees with the statements of Dr. Harry Benjamin on the subject of impotence and its treatment by testosterone appearing in the “Urologic and Cutaneous Review,” Volume 50, page 143, March 1946, and reading as follows [R. 590-591]:

“As for gratifying general results, they were observed in 72% of the cases in the group receiving parenteral treatment, and in 71.4% of the patients who were given methyl testosterone. These figures are in close agreement and indicate that there is no difference in the general response irrespective of the compound administered. Improvement of appetite, gain in weight and physical strength, amelioration of urinary disturbances and increased memory, endurance, ability to concentrate, etc., were frequently observed in both groups.”

He also disagrees with the views of Dr. August A. Werner set forth in the Journal of Urology, Volume 49, page 82, June 1943, entitled “The Male Climacteric: Additional Observations of 37 Patients” and reading as set forth on page 591 to and including page 597 of the record. (We have eliminated quoting that article because of the extensive character of it.) With regard to Dr. Werner’s article, he said that the statements of the author are “*absurd*” [R. 597].

2. EVIDENCE CONCLUSIVELY IMPEACHING DOCTORS HECKEL AND BELT.

Notwithstanding the elaborate tests which Drs. Belt and Heckel both stated were an absolute prerequisite to the prescription of testosterone as reflected in their testimony hereinabove narrated, the following took place with respect to Dr. Belt subsequent to the date on which he gave his direct testimony:

(a) Testimony of Allen H. Parkinson.

On June 24, 1949, Allen H. Parkinson went to Dr. Belt's office on Wilshire Boulevard, arriving there about ten o'clock a. m., asked the receptionist if he could see one of the doctors and was referred to Dr. Ebert, who asked him what he was there for and he told him that he would like some testosterone. The doctor asked him if he had ever taken it before and he replied that he had two years ago in Salt Lake City, that a Dr. Openshaw had prescribed some [R. 866]. He told the doctor that he had been troubled with diminishing of the testicles and penis. The doctor asked him if he was taking it then and he replied "No," but that he continued taking it at frequent intervals because it had a tonic effect and made him feel better. The doctor asked him if a 50 mg. shot of testosterone propionate would be satisfactory and he replied that it would. He was then ushered into another room and in a few seconds a laboratory assistant entered and took a blood sample and left the room and Dr. Belt came in, gave him a brief rectal examination and left. Then another technician came in and injected him with a 50 mg. shot of testosterone propionate. Dr. Belt asked him what he wanted on the prescription, how many tablets he would like. Mr. Parkinson stated that he would like 100 10 mg.

tablets and Dr. Belt said "All right" and had him urinate in three glasses. He asked him how he took them and he replied that he took three or four a day and then maybe laid off three or four days depending upon how he felt and then he resumed [R. 867]. Dr. Belt asked him what the doctor in Salt Lake charged him and he replied "\$5.00" and the doctor said "All right pay the girl \$5.00 on your way out." At that time the doctor wrote a prescription for him, which the witness identified at the time of trial. He paid the girl \$5.00, obtained a receipt and identified the receipt at the trial [R. 868].

(b) Rebuttal Testimony of Dr. Belt.

Dr. Belt's redirect testimony was interrupted during the course of the trial by reason of commitments that he had elsewhere. It was on June 24, 1949, the day after Dr. Belt's first appearance on the witness stand, that Mr. Parkinson made the visit to his office above related. Following that visit Dr. Belt was called to resume his testimony for the Government and undoubtedly in realization of the fact that the prescription given Parkinson was at variance with his former testimony, he gave the following answer to the following question [R. 692]:

"Q. Now, you mentioned the precautionary examinations that were given. Assume for a moment, Doctor, that the patient told you that he was referred by another doctor who gave him such drugs from time to time, would that change the procedure at all? A. Well, if a patient comes to me referred by another physician (436), I always allow the other physician the benefit of whatever doubt that might exist in my mind and my tendency is to go on with the original treatment he has established until I can communicate with him and discuss the problem with him. It is

possible that the patient may not tell me things that he has communicated to his other physician. It is possible that I may not see things in that patient that the other physician saw. So, in the first place, a generously disposed human being would not say right away, 'Oh, your doctor is doing the wrong thing. My goodness, this is the trouble.' But you would conform to the treatment until you had an opportunity for discussion and coming to a common understanding of that."

Then, following Parkinson's testimony, he was called on rebuttal and testified with reference to Parkinson's visit as follows: He treated Parkinson professionally on June 24, 1949. The examination was in his clinic in Los Angeles. Parkinson told him that he had been taking testosterone over a period of about two years. When he went into the room where Parkinson was he reviewed the history which a doctor in his office had taken. Parkinson said that he had been receiving a weekly maintenance dose of 50 mgs. of testosterone. The doctor was testifying from some notes which he said were made at or about the time of the events which they purport to reflect and made in the usual course of business [R. 938]. Parkinson asked him for a prescription for 10 mgs. of testosterone three times a day. He asked for the injections and said he was going to San Francisco and wished to have a maintenance dose to take with him. He said that he had been referred by Dr. Openshaw [R. 939]; that two years prior to that visit his testicles and penis had begun to atrophy and he became sexually impotent; that Dr. Openshaw of Salt Lake City had been treating him with a weekly maintenance dose of 50 mgs.; that he had been away from Salt Lake City for three weeks and his physician recommended that he come to Dr. Belt for treatment.

The doctor stated that he made a complete examination of Parkinson, a complete general physical examination. Parkinson took off his clothes and he examined him by first observing his general makeup, and his eyes, his pupils, his pharynx, his teeth, felt his thyroid, examined his thorax, took his blood pressure, determined his pulse rate and rhythm, felt of his abdomen, looked at his extremities, tapped his reflexes, examined his external genitalia, put a finger in his rectum and examined his prostate and found no contraindications for the use of testosterone [R. 940]. He instructed his technician to take a blood sample and he had already urinated in three glasses and that material was examined. The blood sample was taken because the patient told him that he intended to return and the doctor wanted to know whether or not the acid or alkaline phosphatase had changed. He gave him a prescription for testosterone and he did so because Parkinson had told him that he was under the treatment of Dr. Openshaw of Salt Lake City. He told Parkinson before he began the examination that the reason for it was that they examined people carefully who asked for testosterone or who were getting it to be sure it wasn't doing any harm. He also stated as follows:

“I did not wish, of course, to undermine Dr. Openshaw's authority with his patient. This man presented himself to me as a transient actually under the care of another physician, and it would have been poor policy and poor judgment on my part, as well as poor medicine, to interfere with the activities of his own physician.” [R. 941-942.]

The doctor's notes which he read in testifying were read into the record and showed the following [R. 943]:

“Q. I would like to read into the record, if I may, the portion of it starting down here with [831] ‘Complaint.’

If you want me to read the rest up at the top, I will.

Mr. Neukom: Read any part you want.

Mr. Elson: All right.

Q. Commencing with ‘Complaint,’ ‘Testosterone shots only.’

What is that (indicating)? A. History and physical.

Q. History and physical? A. Wait a minute. Past history.

Q. What is this? A. H. P., past history.

Q. Oh, H. P. A. I guess that is history and present ailment.

Q. H. P. I.? A. History of past illness.

Q. History of past illness. It reads as follows: Two years ago, this man's testicles and penis began to atrophy and he became sexually impotent. Dr. Openshaw of Salt Lake City has been treating him with a weekly maintenance dose or 50 milligram testosterone Neo-Hombreol. He has been away from Salt Lake City for three weeks. His physician recommended that he come here for the same shots. He will be leaving here for San Francisco shortly. Wants oral prescription for Metandren 10 milligram tablets.

On the reverse side, what is this? [832] A. Ear, nose and throat.

Q. What is this up here (indicating)? A. Present illness, ‘P. I.,’ it looks like.

Q. And something here. ‘P. I.’ the doctor says indicates present illness. The nose, ears, eyes and

throat, what is that? A. Tonsillectomy and adenoidectomy.

Q. Tonsillectomy and adenoidectomy. And then over here, 'No venereal disease, no surgery, general health excellent; two children.' What is that (indicating)? A. 'Daughter, age 13—and a boy aged 6 and a girl aged 4.'

Q. Boy aged 6 and girl aged 4. What is that (indicating)? A. 'Living and well.' ”

With reference to the \$5.00 charge for this examination, the Court asked a question and the doctor answered as follows [R. 945]:

“Q. (By the Court): There is just one little item. The witness Parkinson testified that he paid you at your demand \$5.00 for a treatment. How does that correspond with a similar treatment? For a new patient who would not come from another doctor [834]? A. If this patient had not been referred to me from another doctor and if this were not a routine thing, a routine procedure, we would have charged him very much more for this entire procedure. Of course, \$5.00 wasn't the total charge here. We explained to him that the laboratory test would be \$6.50, which he said that he would like to have us bill him for to this false address that he gave us. This is a purely courtesy situation here. A patient comes in; he is being treated by another doctor in another city; we do our best to oblige both the doctor and the patient by carrying on the procedure that the doctor feels is indicated. I asked him what Dr. Openshaw charged him for this treatment and he said \$5.00. As a matter of fact, \$5.00 is close to the cost of 50 milligrams of testosterone propionate. I don't know actually what the cost is to our office from the pharmacy but it is

not under that. We charged him the same thing that his doctor charged him, as a matter of courtesy to that doctor, and we didn't charge him for the physical examination and for the urine analysis; nothing else except for the laboratory test."

(c) Testimony of Hannah Shinglman.

Testified that on June 27, 1949, she went to the office of the Elmer Belt Urologic Group in Beverly Hills [R. 892]. She walked into the office, asked to see Dr. Belt and was told that he was not there. She asked to see another doctor and was told that Dr. LeTourneau would see her. He came into the office and asked what he could do for her and she told him that she and her husband had been here for six or eight months and previous to that time her husband had not been feeling well for the past few years; that he had been very nervous, was jumpy and irritable, and she assumed that he must be going through the male change. She told him that a doctor in Chicago had given her husband some shots and that he had done so well that the doctor had put him on tablets. She showed him a bottle and said that he had run out, and Dr. LeTourneau then gave her a prescription for these tablets which were for 100 testosterone linguets, 25 milligrams, stating that one was to be taken daily. She identified the prescription that she received at that time at the time of trial. Dr. LeTourneau told her that if she liked, perhaps her husband would like to come in for an examination. She told him that her husband was quite busy and in the meantime he wrote out the prescription in her presence [R. 892-894].

(d) Rebuttal Testimony of Dr. Le Tourneau.

Dr. Le Tourneau was called in rebuttal and stated that he was an M. D., a member of the Belt Urologic Group and recognized Mrs. Shinglman as having been in his office on June 27, 1949 [R. 947]. When she came into his office he thought she was a new patient and she told him that a Dr. Willard Shinglman of Cicero, Illinois, was her husband's brother, and that he had directed her to their office and that Dr. Shinglman has been giving his brother testosterone linguets [R. 948]. He advised her that she should have Dr. Shinglman write them a letter regarding the patient, explaining his findings and the need for the linguets and "we would gladly provide a prescription for Metandren linguets" and he gave a prescription for 100 tablets. He did not see her husband at all but told her that she should bring her husband in for an examination [R. 949].

(e) Testimony of Hazen S. Parkinson.

With reference to the testimony of Dr. Heckel which has hereinbefore been narrated, and particularly with respect to the tests that are and should be administered prior to prescribing testosterone, the following evidence was introduced by the defendants:

Hazen S. Parkinson, the father of Allen H. Parkinson, drove to Chicago with his son and arrived there June 27, 1949 and went to the office of Dr. Norris J. Heckel shortly after one o'clock in the afternoon. He told the nurse in Dr. Heckel's office that he wanted to see Dr. Heckel [R. 898-899]. In a few moments she took him into another room and a few moments later the doctor came in. Mr. Parkinson introduced himself, showing him a bottle with a label on it "Metandren Linguets, 500" and told him he wanted to get the bottle refilled. He showed him a pre-

scription that he had from Dr. Openshaw for testosterone by injection. He told Dr. Heckel that he was going on a ship [R. 904-905]. The doctor stated that he had just come from Los Angeles from a trial [R. 905]. Mr. Parkinson asked him if there was anything wrong with taking the tablets, anything that would be dangerous, that if there was he didn't want them, and the doctor replied, "Oh, no, I don't know as they will do you any damage, but we don't want them sold over the counter." The doctor had him urinate in a glass and he placed his finger in Mr. Parkinson's rectum and wrote out a prescription for him in his presence. Nothing was said by the doctor on the subject of fertility or sterility. He told the doctor that on the ship he would be rooming with other men. When he told him that he wanted 500 tablets the doctor remarked that that was quite a few, that they were expensive, and Mr. Parkinson replied, "Well, if you have ever been on a ship, there are three or four men to a room and every time you take a pill someone else wants one." [R. 906.] The doctor asked him how he took them and he replied one or two a day, according to how he felt, and the doctor replied that he would put down one a day and he could take them the way he had taken them before. About five or six minutes was consumed from the time he walked into the doctor's office until he walked out with the prescription [R. 906-907]. Mr. Parkinson at the time of his visit to Dr. Heckel was 65 years old. He showed him his Merchant Marine card [R. 908]. He told Dr. Heckel that he was trying to go to sea and that he was gone from this country for long periods of time when he got on a ship and that he wanted enough testosterone for a year not only for himself but such other sailors who might want one now and then [R. 911]. Dr. Heckel absolutely did not tell him to report to his physician at regular intervals [R. 912].

(f) Dr. Heckel's Letter in Rebuttal to Hazen S. Parkinson's
Testimony.

In the interests of saving time, counsel for the defendants stipulated with the Government that if Dr. Heckel were called on rebuttal he would testify in accordance with the letter sent by him to Government counsel following Mr. Parkinson's visit to him. The stipulation was as follows [R. 923]:

"It is stipulated and agreed that, if Dr. Norris J. Heckel were present and sworn as a witness to testify, and did so testify, he would testify that, on June 27, 1949, a Mr. Parkinson came to his office in Chicago and stated that he had been referred to by a former patient. Parkinson said that he was 72 years of age, a sailor by occupation and gone from the country for long periods of time; that he was in Chicago as a transient; that his doctor in Salt Lake City had been giving him a prescription for methyl testosterone and that he had been taking this drug under his doctor's direction for the past several years; that he was leaving the country and needed about a year's supply of testosterone and requested a prescription for a year's supply. He showed Dr. Heckel a prescription for testosterone issued by another doctor. Dr. Heckel then made a physical examination of Parkinson, which included a urine analysis and a rectal examination of the prostate and found no contraindication to the use of testosterone; he found that Parkinson's prostate was of normal size, shape and consistency, with no evidence of prostatitis; and that he then renewed Parkinson's prescription for methyl testosterone linguets and advised him to report to his physician at regular intervals."

3. THE EVIDENCE OF ALLEN H. PARKINSON AND HAZEN S. PARKINSON, COMPLETELY AND INCONTROVERTIBLY REFUTED THE TESTIMONY OF THE GOVERNMENT WITNESSES ON THE SUBJECT OF TESTS GIVEN BY THE GENERAL PRACTICING PHYSICIAN PRIOR TO PRESCRIBING TESTOSTERONE.

(a) Testimony of Allen H. Parkinson.

Allen H. Parkinson testified that on June 30, 1949, he called at the office of E. A. Gummig at Pasadena, California [R. 869] and asked for and received a prescription for 100 methyl testosterone linguets; that at no time during his visit did the doctor lay any hands upon him and he was not in Dr. Gummig's office over a minute [R. 870].

(b) Testimony of Hazen S. Parkinson.

During the course of Hazel S. Parkinson's testimony at the trial of the criminal actions, an offer of proof was made as follows [R. 902-904]:

"I also offer to prove that Mr. Parkinson called on several doctors, on the dates mentioned on certain prescriptions, throughout parts of Los Angeles County, and talked at random; that in each instance he went into the doctor's office, told the doctor that he wanted this same bottle, the one he used when he saw Dr. Heckel, refilled, and asked for a prescription; that in each instance he received a prescription for [764] these linguets and on no occasion was anything said to Mr. Parkinson about sterility or fertility or cancer of the prostate, nor did any of the doctors lay a hand on him, and he did not call on any doctor who turned him down on the request for a prescription.

“The doctors that would be subject to Mr. Parkinson’s testimony in that regard would be Dr. G. G. Ferbryck, M. D., 516 Professional Building, 117 East 8th Street, Long Beach, California, who wrote out a prescription for Metandren Linguets, one a. m. and p. m., and the date was June 29, 1949; Dr. Wayne P. Hanson, in the same building, on June 30, 1949, wrote out a prescription for 500 10-milligram Metandren Linguets, directions, one linguet daily; that he also called on Dr. George D. Stilson and Dr. Milo Ellik, together in the same office, 511 Professional Building, 117 East 8th Street, Long Beach, on June 30, and received a prescription from Dr. Ellik for 500 Metandren Linguets, directions, as directed; that he called on Dr. Raymond W. Kelso. On June 31, 1949, the doctor’s address being 117 East 8th Street, Long Beach, who wrote out a prescription for 250 10-milligram Metandren Linguets, with directions, dissolve one on tongue each day; that he called on George B. Hanson, M. D., 716 Professional Building, 117 East 8th Street, Long Beach, on June 30, 1949, received a prescription for 250 Metandren Linguets, 10 milligrams, directions, one per day; that he [765] called on Dr. H. F. Gramlich on June 30, 1949, address, 117 East 8th Street, Long Beach, and received a prescription for one bottle of Metandren Linguets, directions, as directed; that he called on Dr. P. W. Prince of the Bishop Clinic Staff, 117 East 8th Street, Long Beach, on June 30, 1949, and received a prescription for 250 10-milligram Metandren Linguets, directions, I guess it is, one daily, dissolve in mouth; that he called on Dr. L. L. Wiltse, 714 Professional Building, 117 East 8th Street, Long Beach, on June 30, 1949, and received a prescription for 500 Metandren Linguets, directions, take as directed; that he called on Dr. Marvin R. Lauer, 829 East Compton

Boulevard, Compton, California, on July 2, 1949, and received a prescription for 500 Metandren Linguets, 10 milligrams, directions, use as directed; that he called on Dr. Francis J. Ort, 107 North Santa Fe Avenue, Compton, California, on July 2, 1949, and received a prescription for 500 Metandren Linguets, directions, two daily; that he called on Dr. L. C. Lowe, 706 South Hill Street, Los Angeles, on July 1, 1949, and obtained a prescription for 500 Metandren Linguets, 10 milligrams, directions, as directed; that he called on Dr. Glenn E. Jones, 403 West 8th Street, Los Angeles, on July 1, 1949, and received a prescription for 500 Metandren Linguets, 10 milligrams, directions, one or two per day; that he called upon Dr. R. L. Byron, 1015 Chapman Building, 756 South Broadway (766), Los Angeles, on July 1, 1949, and received a prescription for 500 Metandren Linguets, 10 milligrams, directions, one as directed."

At that trial the offer was refused. However, in the stipulation as to the record in the injunction proceeding, No. 10391-HW, it was stipulated that:

"If Mr. Hazen S. Parkinson were called to testify in this proceeding, he would testify, if permitted, in accordance with the offer of proof set forth on pages 762-767 of the transcript of record in the criminal trial [R. 269]."

(c) Stipulation re: Further Evidence of General Practicing Physicians.

A stipulation was entered into by counsel for the purpose of conserving time and this stipulation was as follows [R. 929]:

"Mr. Danielson: If the court please, in an effort to conserve time, again, it is agreeable between

counsel for the government and counsel for the defense that the government could produce additional general practitioners who would (810) merely serve to corroborate the testimony of Dr. Terrill, and likewise, that the defense could produce additional general practitioners who would tend to corroborate their general practitioners, and we are willing to stipulate as to that fact and to eliminate further testimony of this nature.”

That stipulation would, of course embrace as well the testimony of the defense doctors which now follows:

4. TESTIMONY OF DEFENSE WITNESSES.

(a) Dr. William A. Swim.

Was called as a witness for the defense. Is a Doctor of Medicine, received his degree in 1915, has been connected with several hospitals, commenced practice in Los Angeles in 1918 and has specialized in internal medicine since that time. Internal medicine consists of the diagnosis and treatment of non-surgical diseases, non-obstetrical. He was formerly a member of the Board of Medical Examiners of the State of California [R. 835-836]. If a male in middle life comes to him and complains of nervousness, flushes, sweats, chills, general weakness, lack of physical strength, impaired memory, inability to concentrate on activities and a tendency to evade them, his practice in dealing with that patient and those symptoms is to take a general history of the person and past illnesses. He makes a physical examination, including the head and neck, chest and abdomen, prostate and rectum reflexes, general appearance of the skin and if he finds no evidence of disease of a specific nature he prescribes testosterone or administers it. He has done so on many occasions and

since there has been testosterone, which has been for the last ten years, in commercial quantities, he has done so, all with an ever increasing number of cases and on many of those occasions he has found that after administering the drug the person's symptoms appeared relieved. On no occasion on which he has ever administered it has he ever encountered any adverse results [R. 835-837]. He associates the male climacteric with a diminution of the secretion of the interstitial cells of the testicle. This usually occurs in men around 50 who complain of fatigue, lack of concentration, loss of memory, loss of appetite, sleeplessness, sometimes a sense of heat in the body and profuse perspiration [R. 837-838]. His attention was called to the elaborate procedures which the Government witnesses testified were necessary to be followed prior to the administration of testosterone and he stated that he did not follow those procedures but rather he would do just what he had said he would do [R. 838-839]. In his opinion the attitude of the average patient would be to refuse to follow such elaborate procedures if they were suggested to him as conditions precedent to the administration of the drug [R. 839] and that he would go to some other doctor who would not go through that procedure [R. 840]. In his practice he prescribes testosterone approximately once a week and has injected testosterone propionate into other doctors on more than one occasion and prior to such injections he did not conduct a rectal examination nor did the doctor patients ask for it [R. 840-841]. He does not share the opinion of Dr. Heckel that men in middle life do not generally have a deficiency of the male sex hormone because their concentration of hormones is below its maximum. With reference to the individual to whom he would administer or prescribe testosterone if the individual came back to him in three

or four weeks and the symptoms had disappeared or seem relieved, he would conclude that he had supplied with a hormone in which he had been deficient. If the symptoms were not relieved he would change the dose and if that kept on and no result was accomplished he would try something else [R. 840-841]. It is not his practice to conduct the elaborate tests testified to by Dr. Heckel and he is unaware of any other doctors in this locality that conform to such tests. Never in his experience has he performed a biopsy of the prostate to determine the presence of cancer and such a biopsy if made would not be conclusive in that part of the tissue that might be taken out might not be the part affected [R. 842]. He very seldom encounters cancer of the prostate and he thinks that he has seen three in his thirty years of practice. He disagrees with the testimony of Dr. Heckel as to what the general practitioner would do in the way of tests on which an individual complaining of nervousness, etc. prior to the administration of testosterone [R. 843-844] and he has never conducted such tests before prescribing the product and has never known of any other doctor who has done so other than in the experimental field. He has read articles on the subject of testosterone in its relation to cancer of the prostate and as a result of his reading it is not his opinion that it will accelerate the growth of such a cancer, or, within the doses involved, be dangerous [R. 843-844]. It would be impossible to know how much testosterone over and above that which the individual naturally produces would accelerate cancer of the prostate if it would at all, because cancer has no particular line of progress. It is the one lawless thing in human pathology. It may lie dormant for many years and may flare up without any provocation, grow rapidly

and destroy life in a very short time. The pathology of cancer is not understood and there is no orderly procedure of it [R. 845-846].

He has never found 25 to 50 mgs. of methyl testosterone daily to induce sterility [R. 846]. With reference to the testimony of Dr. Nelson that the effect of testosterone upon the sperm producing activities is determined by a biopsy, taking out a tissue of the testes, Dr. Swim stated that he knows of no instances where that has been done notwithstanding Dr. Nelson's statement that it was very widely done today [R. 847-848]. He has read some of the literature on the subject and in his opinion as a result of that reading testosterone will not affect sterility, and such of the literature as he has read is divided on the question [R. 848-849].

(b) Dr. George E. Fakehaney.

Testified as a witness for the defense. Graduated from Loyola University in Chicago in 1937 with the degree of M. D. *cum laude*. Was resident physician at the Good Samaritan Hospital, Los Angeles in 1939, and has been admitted to practice in California since 1938. Is a member of the Los Angeles County Medical Association and Hollywood Academy of Medicine [R. 740-741]. Is engaged in general practice as a medical consultant or examiner for Technicolor Motion Picture Corporation, Samuel Goldwyn Studios, and Radio Corporation of America [R. 742]. In his practice has never used a blood or urine test for detecting cancer of the prostate. Doctors in general practice do not use that type of examination. He knows of no other examination besides rectal examination commonly used by doctors in this locality to detect cancer of the prostate [R. 743]. He has read literature on

the subject and some of it suggests that methyl testosterone might possibly aggravate a cancer of the prostate but the literature is not uniform on the subject. There is much confusion on the subject. He has encountered cancer of the prostate on an average of about once a year [R. 744]. During the war he gave thousands of physical examinations. Among other things, he was the doctor who gave them for the Hughes Aircraft Corporation and he conducted an average of 20 to 25 per day and he found no cancer of the prostate to exist except on very rare occasions [R. 745]. He has prescribed testosterone in his practice on an average of about once a day and has never encountered any adverse results from the use of it [R. 745]. He has experienced no danger in the use of testosterone [R. 746]. Testosterone is commonly given to a patient anywhere from 45 to 70 who complains of unusual weakness, loss of memory, etc. It is given particularly when there is nothing else that you can point to as causing the symptoms. When a patient calls on him and complains of those symptoms, he usually talks with him for a few minutes to see if there is anything else that bothers him, or whether he has had any type of medical care and if he determines that the patient does not have any organic pathology he prescribes or injects the male hormone and tries it for a certain period of time. Usually a month's supply. Many of the persons for whom he has prescribed it have obtained benefits and some have not and in the latter case he determined that the hormones were ineffective in their cases, that is, they were not suffering from hormone deficiencies. That it quite the usual procedure in the practice of medicine. In the practice of medicine to a large extent it is a method of trial and error to follow a certain course of treatment to see whether it will be beneficial [R. 748-749].

With reference to the testimony of Dr. Huggins [R. 566] that *"occasionally we are forced to do things to human beings in a few cases to make a few observations that are not strictly in the patient's best interests"* it was not his practice to experiment with patients. That is done in laboratories [R. 751]. In his practice he finds impotence on occasion to be psychogenic in origin and sometimes not, but he has prescribed testosterone for persons who complained of impotence and has had on occasion good results [R. 752]. With reference to Dr. Heckel's statement that the administration of testosterone would destroy the seminiferous tubules, it has very rarely been mentioned to do that and he does not know how it could be proven, particularly when you are dealing with a human being [R. 752-753]. He knows of no doctors in this locality who submit patients to the tests mentioned by Dr. Heckel [R. 753]. He has never heard of any doctor performing a biopsy of the prostate and it is certainly not common practice to do so. A biopsy of the prostate is commonly done by inserting an instrument through the penis and cutting a piece of the prostate gland [R. 754-755].

(c) Dr. Paul E. Travis.

Graduated University of Southern California, A. B. 1941, Phi Beta Kappa, University of Iowa 1942, Masters degree in physiology, M.D. degree University of Southern California 1946. Two years in the service at the Veterans Hospital, Arizona, returning to private practice 1948. Has used testosterone in his practice and used it at the Veterans Hospital. Is familiar with the male climacteric. The symptoms usually associated with it, loss of libido—sexual drive—loss of a feeling of sense of well being,

nervousness, irritability, sleeplessness, has had many patients of middle age complain of those symptoms, and on some of those occasions has prescribed testosterone [R. 788-789]. Some of those patients after they returned following treatment appeared very definitely relieved [R. 790]. With men to whom he has prescribed it, they appear to sleep better, gain weight—those who have been losing weight—improves the appetite, imparts a general sense of well being and better able to concentrate. When a person complains to him of such symptoms, he tries him out on the drug and if it helps him he concludes that the man suffers from male hormone deficiency [R. 791]. The usual doses are 25 to 50 mgs. per day in tablet form. With regard to the tests mentioned by Dr. Thienes that would be followed by a general practitioner, he stated that a general practitioner does not have the time nor does the patient usually have the funds to undergo such expensive laboratory determinations and he never does it and he knows of no other doctors that do so. In the practice of medicine it is common to diagnose a person's condition and give him what he thinks will relieve him and if that does not work try something else. That is the practice of medicine [R. 792-793].

At the Veterans Hospital many of the patients were hospitalized and many were veterans past middle age, with concomitant physical ailments, such as asthma, etc., whom they felt would be given added energy perhaps to make them ambulatory if given testosterone. They were given testosterone and their amount of energy increased as well as their sense of well being and they improved. Prior to

giving testosterone to such patients, they just gave them a general physical examination, eye, ear, nose, throat, heart, lungs, abdomen and prostatic. A prostatic examination takes about thirty seconds. In his experience he has never encountered any adverse results in the use of testosterone [R. 794]. He does not agree with Dr. Heckel that males of middle life do not suffer from a deficiency of the male hormone and has found the contrary to be his experience. He does not follow the elaborate tests mentioned by Dr. Heckel because that has to do with a specialist's laboratory [R. 795]. The 17 ketosteroid test is a rare test and he knows of no doctors in his section of town who make that test prior to prescribing testosterone. He has never performed a biopsy upon a person's prostate to determine whether it was cancerous but he has referred patients to a urologist if he suspected cancer. He knows of no general practitioner who performs such a biopsy and if a doctor suggested it to a patient the patient would probably never come back [R. 796-797]. With respect to the elaborate tests mentioned by Dr. Heckel, he said that no general practitioner could afford to follow that test on any patient before giving him such a simple medicine as testosterone and he knows of no doctors who do [R. 798-799]. He has read literature concerning testosterone and its relationship to cancer of the prostate. The articles are pro and con on the subject. Based on what he has read and from his experience, he absolutely does not consider testosterone to be dangerous [R. 799-800]. With regard to the literature received from the three principal manufacturers of testosterone, he considers it authentic and states that it is the practice of other doctors that he knows of to rely upon it as it is one of their main sources of current information.

(d) Testimony and Affidavit of Martin A. Clemens.

Is a pharmacist, admitted in 1927, and purchased testosterone from Roche-Organon Company, Ciba Pharmaceuticals Supply and Schering Corporation, and received literature from those corporations in connection with the products purchased from them [R. 696-697]. Since 1943 he has sold between 4,000,000 and 5,000,000 tablets of testosterone. Originally they were sold in boxes of 15, 30 and 100 and later the manufacturers changed them to 30, 100 and 500. A very small percentage of his business comprised the 15 tablets to a box containers—about 20%—about 70% comprised the sale of the boxes containing 30 tablets to a box and about 10% comprised the sale of 500 to a box [R. 698-700].

With regard to the Government's Exhibit 18 [R. 983], which was a letter from Roche-Organon, Inc., the witness stated that notwithstanding the letter, the literature supplied by the manufacturer with the product purchased by him was supplied to him in large numbers [R. 719]. He was told by the manufacturers' managers to ignore the letter, that it was merely put out to appease the medical profession and they kept supplying him with other literature from then on [R. 735]. They said that they had to keep the product council-accepted with the medical profession [R. 735-737].

By the stipulations as to the record in both consolidated cases [R. 266, 150], the affidavits of Martin A. Clemens [R. 55], the supplemental affidavit of Clemens [R. 119], and other supplemental affidavit of Clemens [R. 107] were made part of the record in the case before the court in the injunction proceedings, as well as the affidavit of Eugene M. Elson [R. 49]. The affidavits of Allen H. Parkinson were likewise made part of that record.

In the affidavit of Clemens [R. 55] was set forth an analysis of the charges made in each of the counts and the information in the criminal action, No. 20596, Criminal [R. 56-64]. No affidavit was submitted in opposition to that analysis. Following that analysis a recapitulation of the charges was set forth in Clemens' affidavit, reading as follows [R. 64-65]:

"Recapitulating the aforesaid charges insofar as the same are material to this litigation, the charges of the government [in the criminal case] were that the labeling of said products so shipped constituted a misbranding of said products for the following reasons:

1. That said labeling falsely represented and suggested that said products would be efficacious in the treatment of the conditions enumerated hereinbefore under the discussion as to Count I in violation of Section 502(a) of the Food; Drug and Cosmetic Act.

2. That said labeling failed to bear adequate warnings against use in those conditions where it might be dangerous to health in that the labeling failed to warn that its use might result in sterility and its use by individuals with early and incipient carcinoma of the prostate might result in acceleration of the malignant growth.

3. That said product was dangerous to health in that 25-mg. thereof as prescribed: 1-2 tablets daily, [59] would be dangerous to health in the aforesaid respects in violation of Section 502(j) of said Food, Drug and Cosmetic Act."

Clemens pointed out in his affidavit that during the criminal action he took the position that the symptoms referred to in Exhibit A attached to his affidavit [R. 101] and which was the subject of the mislabeling charge in

the criminal action, did no more than represent that the male hormone product would be efficacious in the treatment of those symptoms if the individual were suffering from a male hormone deficiency [R. 65]; that in support of the charges contained in the information, witnesses testified in substance as set forth in the affidavit [R. 66-94]. In his affidavit he alleged that immediately following the judgment of conviction he consulted with legal and other counsel with respect to the relabeling of the product "so as to conform to the objections made by the Government and disclosed by Government evidence in said criminal action" [R. 95] and in order to meet the objections so made by the Government during the course of that trial all of the former labeling was discarded and an entirely new label was redrafted [R. 95-97]. A copy of the labels so redrafted are attached to that affidavit as Exhibit B [R. 105].

Responding to the allegations in the complaint for injunction in action No. 10266-HW that 5 milligrams linguets of testosterone have no therapeutic value, he quoted from the United States Pharmacopoeia, listing the dosage of methyl testosterone as follows [R. 98]:

"Average dose: sublingual, 5 milligrams."

He quoted from the 14th Edition of "Useful Drugs, 1947" of the American Medical Association listing under methyl testosterone the average dosage:

"Dosage: Average dose, sublingual, 5 milligrams."

He also quoted from the American Medical Association publication "Epitome of the Pharmacopoeia of the United States" and from the "National Formulary, 8th Edition" listing under methyl testosterone the same dosage.

He alleged that the relabeling of those products as represented by Exhibit B was done in good faith and under expert counsel and advice to comply with the particulars in which the former labeling was contended in said criminal action to be deficient [R. 98].

With reference to the allegations of paragraph VI of the complaint for injunction in action No. 10266-HW [R. 5] he alleged that shortly after the judgment in the criminal action certain window and store displays remained there which had been there prior to the institution of the criminal action and this was because of the press of business imposed upon him in attempting to organize his business in such a manner that it would comply with the evidence and the judgment in the criminal action, but that at the time of the filing of the complaint in the injunction action all of those store displays had been taken down [R. 99]. He denied that in any advertising since the judgment in the criminal action had he represented in newspaper advertising that these drugs would be efficacious in alleviating a variety of diseases conditions or those relating to sexual impotence in men or change of life in women and he attached as Exhibit "C" [R. 106] a correct copy of the only advertisements that had appeared in any newspapers since the date of the judgment in the criminal action up to the date of his affidavit, October 14, 1949 [R. 99-100].

Mr. Clemens also submitted a supplemental affidavit [R. 119] in which he stated that with respect to the allegations in the complaint for injunction that 5 milligrams

per day of methyl testosterone have no therapeutic value [Paragraph X, Complaint for Injunction; R. 7], no charge or claim was made in the criminal information that 5 milligrams of this product had no therapeutic value, though Counts 12, 13 and 14 of the information [R. 315-323] concerned a 5 milligram product. He also alleged that the prescription received by Hazen S. Parkinson from Dr. Norris J. Heckel was 5 milligrams per day.

Another supplemental affidavit was filed by Mr. Clemens in the injunction action alleging a purchase by him of 3 bottles each of Dr. Pierce's Favorite Prescription, Dr. Pierce's Golden Medical Discovery, Dr. Miles Nervine and Lydia E. Pinkham's Vegetable Compound [R. 107]. Attached to that affidavit was the carton in which one of the bottles of Dr. Pierce's Favorite Prescription was contained and this carton was Exhibit A to that affidavit [R. 109]. Enclosed within the carton was a pamphlet attached to the affidavit as Exhibit B [R. 110-111]. Also attached to the affidavit was the carton in which the bottle of Dr. Pierce's Golden Medical Discovery was contained and this carton was attached as Exhibit C [R. 112]. The carton in which the Lydia E. Pinkham Vegetable Compound was contained was attached to the affidavit as Exhibit D [R. 113]. Inside the carton of this product was a circular attached to the affidavit as Exhibit B [R. 114-115]. The carton in which Dr. Miles Nervine was contained was attached as Exhibit F to the affidavit [R. 116] and the circular within the carton was attached as Exhibit G [R. 117-118].

(e) Affidavit of Allen H. Parkinson.

An affidavit was filed by Allen H. Parkinson in the injunction action, No. 10391-HW [R. 199]. Mr. Parkinson analyzed in detail the counts of the information in the criminal action, No. 20642-HW, in which he had been a defendant [R. 200-205]. He alleged that no charge was made in that information that adequate warnings against the use of those products under certain conditions did not appear on the labeling and that his labeling contained a warning statement was apparently deemed sufficient by the Government [R. 205]. There was also attached to his affidavit as Exhibit A the leaflet that had been the subject of the mislabeling charge in the criminal action [R. 243]. There was also attached another leaflet subject of the charge in the criminal action, as Exhibit B to his affidavit, in which a warning statement appeared which was apparently deemed sufficient by the Government in that action [R. 249]. He recapitulated the charges in the information against him so far as material to the injunction case as follows [R. 206]:

“Recapitulating the aforesaid charges insofar as the same are material to this litigation, the charges of the Government were that the labeling of said products so shipped constituted a misbranding of said products for the following reasons:

1. That said labeling falsely misrepresented and suggested that said products would be efficacious in the treatment of the conditions enumerated [202] heretofore as to Count I in violation of Section 502 (a) of the Food, Drug and Cosmetic Act.

2. That said labeling failed to bear adequate directions for use in that the directions contained on the label of the bottle were not adequate directions for use.”

He also alleged that during the criminal action he took the position that the symptoms referred to in Exhibits A and B attached to his affidavit [R. 243-249] would be relieved if the individual manifesting same were suffering from a male hormone deficiency and that these leaflets did no more than make such a representation [R. 206]. In his affidavit he likewise summarized the testimony of the witnesses in the criminal action whose testimony appears in the transcript which was made part of the record before the court in the injunction action [R. 208-232]. He likewise alleged in his affidavit that following the judgment in the criminal action he consulted with expert counsel on the subject of relabeling so as to conform to the objections of the Government as disclosed by the Government evidence in the criminal action [R. 232]; that the labeling employed by him prior to the criminal action was discarded:

“In order to eliminate the objections of the Government that said product should not be continued over a period of time unless under the supervision of a physician, in that sterility might be caused thereby or a carcinoma of the prostate might be accelerated in growth thereby, affiant caused to be placed on said label, among other things, language to the effect that said product should be taken, 1 tablet upon arising before breakfast, or 1 tablet shortly before retiring, and that ‘the maintenance dosage can be extended from 3 to 6 months *under the supervision of a physician*. (Emphasis added.) [R. 234].

“In order to overcome the objections made by the Government in said criminal action that an individual layman could not diagnose his need for said product, affiant caused also to be placed upon said label directions as follows:

“‘For use by adult males deficient in male hormone *when small dosages of male hormone are prescribed or recommended by a physician, for palliative relief of such symptoms.*’ (Emphasis added.)

“As a further caution to users of said product that a physician should be consulted for the purpose of determining whether or not the symptoms manifested were the result of a male hormone deficiency, and further, explanatory of the label language above referred to that the product was to be used when ‘prescribed or recommended by a physician,’ affiant caused to be added to said label the following:

“‘It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted since testosterone will not aid or relieve symptoms not associated with male hormone deficiency.’”

He also alleged that in order to meet the objections and the testimony of some of the Government witnesses in the criminal case that should testosterone be taken by young men desirous of stimulating their sexual desire and ability, it might result harmfully to them unless under the guidance of a physician, he caused to be placed upon the labeling, the following [R. 235]:

“Children and young adults *must not use except under constant direct supervision of a physician.*” (Emphasis added.)

He also alleged in his affidavit that [R. 235]:

“In order to meet the objections of the Government and the testimony of witnesses produced by the Government in said criminal action in the case of United States v. El-O-Pathic Pharmacy, *et al.*, Claim No.

20596, that the labeling involved therein did not contain adequate warnings against the use of said product when carcinoma of the prostate was indicated and without adequate warnings of the use of said product might cause sterility, affiant caused to be placed on said labeling the following cautionary (226) language, and discarded the cautionary language formerly employed by him and contained on Exhibit 'A' and 'B' hereto (to which no objection was made in said criminal action):

“The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate, or by anyone with cardiovascular disease, defects of spermatogenesis, sterility whether absolute or partial, or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. *Take only as directed.*’” (Emphasis added.)

With respect to the allegation in the complaint for injunction that linguets of 5 milligrams had no therapeutic value, paragraph VIII, Complaint [R. 171], he likewise referred to the same references as set forth in the affidavit of Clemens to the United States Pharmacopoeia the 14th Edition of “Useful Drugs, 1947” of the American Medical Association, and the publication of the American Medical Association entitled “Epitome of the Pharmacopoeia of the United States” and also the “National Formulary, 8th Edition” in which 5 milligrams was the suggested dosage [R. 236-237]. He also alleged that in the criminal action against him, No. 20596, Criminal, paragraphs 12, 13 and 14 [R. 315-323] involved linguets of 5 milligrams but that

no charge was made in that information or during the course of trial that linguets of 5 milligrams had no therapeutic value [R. 237].

Mr. Parkinson also alleged in his affidavit [R. 230] that following the complete revision of his labeling he mailed circulars to retail druggists throughout the United States soliciting their business for the purchase from him of the product so relabeled. In this connection he mailed thousands of circulars to retail druggists doing business solely within the state of California; that the majority of these druggists were members of the Southern California Pharmaceutical Association, Ltd., and that these druggists requested advice of that association whether such product might be sold by them over the counter without a prescription; that these inquiries were prompted by reason of the fact that following the conclusion in the criminal action articles appeared in national and local drug journals advising of the outcome of the criminal actions and stating that as a result of the judgment therein the product could not be sold except on prescription; that upon receipt of said inquiries from these druggists, the Southern California Pharmaceutical Association, Ltd., on September 15, 1949, addressed a letter to Robert S. Roe, Chief of the Los Angeles District of the Food and Drug Administration enclosing copy of the circulars sent to these druggists by Mr. Parkinson and stating that their members requested advice as to whether the products could be sold over the counter without being subject to prosecution by the Food and Drug Administration; that within a few

days after receipt of that letter, Mr. Roe addressed a letter, in words and figures as follows [R. 241]:

“Dear Mr. Baird:

“I have your letter of August 29, transmitting copies of advertising folders that have been distributed to Pharmacists throughout Southern California. This material offers Hormones for over the counter sale and you request my comment on the application of the Federal Food, Drug and Cosmetic Act.

“It is our view that products containing significant amounts of hormones are not suitable for over the counter distribution, because adequate directions for use and adequate warnings can not be devised that will enable the safe and effective use of such products by the lay person. Consequently, such preparations should be reserved for prescription use. The over-the-counter sale of such products received in interstate commerce would constitute a violation of the Federal Act.

“It is our view that products containing Therapeutically insignificant amounts of hormones would be worthless and labeling (231) representing them as hormone preparations or as preparations intended for use in treating hormone deficiencies would be misleading.

“Very truly yours,

ROBERT S. ROE,
Chief, Los Angeles District.”

Mr. Parkinson then alleged that following the exchange of correspondence mentioned, copies of the two letters referred to were sent to all member retail druggists and appeared as well in national and local drug journals. He alleged on information and belief that the Food and Drug Administration had formed a policy to prevent the sale of

methlyl testosterones except on prescription, whether or not there was any statute, rule or regulation preventing the sale except on prescription; that the Food and Drug Administration intended to continue to harass, annoy and oppress him by vexatious litigation in order that this policy might be carried into effect and in order that he might be placed in a position where he could no longer continue financially; that Mr. Roe's letter was calculated and intended to destroy Mr. Parkinson's retail outlets during the pendency of this litigation notwithstanding the fact that any and all transactions had or contemplated between Mr. Parkinson and druggists in California would be intrastate transactions and wholly removed from the jurisdiction of the Food and Drug Administration, and that Mr. Roe in his reply did not intimate or suggest that the question which was the subject of his letter was the question at that time and now involved in litigation before this court [R. 242-243].

(f) Affidavit of Eugene M. Elson.

An affidavit was filed in the injunction case, No. 10266-HW, by Eugene M. Elson, defense counsel [R. 49]. He alleged that he obtained from the Clerk of the United States District Court in which the action was pending the file in *U. S. v. Walter Kurt Max Hassenstein*, No. 19004, Criminal, that he examined all of the documents in the file and copied therefrom certain portions of those documents, that the defendant in that action was prosecuted for a violation of Sections 352(f)(1) and 352(f)(2), United States Code, the corresponding sections of which in the Federal Food, Drug and Cosmetic Act are Sections

502(f)(1) and 502(f)(2); that the information quoted the labeling involved as follows [R. 50-51]:

“Rx 5000

“Important

“To be used as directed by physician. Not to be used by children or when pregnant or (46) in the presence of serious diseases like diabetes, tuberculosis, cancer or when abdominal pains (stomach-ache, cramps, colic), nausea, vomiting (stomach sickness) or other symptoms of appendicitis are present. Ampules should not be used in cases of nephritis, myocarditis and arteriosclerosis and threatened rupture of the uterus. Frequent or continued use of this preparation may result in dependence on laxatives. * * *.”

This affidavit further alleged that the information charged that Section 352(f)(1) U. S. C., was violated in that the label failed to reveal the reason for using the drug; that Section 352(f)(2) U. S. C., was violated in that the “drug contained a solution of Posterior Pituitary and the statement, to-wit ‘should not be used in cases of nephritis, myocarditis and arteriosclerosis’ in the labeling was not adequate to warn against use of the drug in kidney disease, heart disease and hardening of the arteries, and in that the labeling of said drug bore no warning against use by persons with high blood pressure,” that a motion to dismiss was filed with supporting points and authorities; that the Government filed points and authorities in opposition thereto which stated in part [R. 51-53]:

“With respect to the alleged misbranding in violation of Section 352(f)(1) (Section 502(f)(1), Federal Food, Drug and Cosmetic Act) defendant rests his Motion to Dismiss upon the contention that nothing in that Section of the Act requires the labeler

to reveal the reason for the use of (47) the article, particularly since the labeling contained the statement that the preparation was to be 'used as directed by physician.' Plainly, if it is required that the labeling set forth the reasons or conditions for which the drug is to be used, such requirement is not fulfilled by a statement that it is to be used as directed by a physician. Moreover, such a direction is ambiguous and provides no assurance that the purchaser will consult a member of the medical profession. The regulations promulgated under Section 352(f)(1) (502(f)(1), Federal Food, Drug and Cosmetic Act) provide for an exemption of the requirement that the labeling contain adequate directions for use if, among other things, the labeling of the drug bears the statement 'Caution: To be dispensed by or on the prescription of a physician (21 Fed. Reg. (Com. Supp.) Section 2.106(b)(4)).' Defendant has not taken advantage of this exemption but, rather, has carefully avoided it. Compliance with the requirements of the exemption would assure the direction and guidance of a physician in the use of the drug. The statement, however, placed on the drug by defendant does not, as stated, give any such assurance. Thus, the situation presented is apparently one where the drug is so dangerous in its use that the advice of a physician is ambiguously suggested, but the language which would insure the drug's use on the instruction of a (48) physician is absent."

That the points and authorities of the Government continued further at considerable length on the theme that Section 352(f)(1), U. S. C., required labeling to state the conditions under which it was to be used and that the warning on the labeling used words unknown and "mysterious" to the average user. In reply to the Gov-

ernment's points and authorities, the defendant filed further points and authorities, stating in part that [R. 53]:

"When there is taken into consideration also the fact that the pleading sets forth that the product is to be used 'as directed by physician,' there can be no intimation that the statement was not inserted as a warning against the use of the product except as designated by the physician * * *."

The defendants' points and authorities further stated in part:

"The matter of describing cases of 'nephritis, myocarditis and arteriosclerosis' and the allegation that these diseases should be described as 'kidney, heart disease and hardening of the arteries, respectively, has no precedence in our law. It would cause a criminal act to arise if, in the whimsy or caprice of a Government official the identical words approved by the Government were not used, * * *."

Thereafter the District Court rendered its opinion entered in the minutes of the court as follows [R. 54-55]:

"Hall, J.:

"The statement on the label 'Important. To be used as directed by physician,' is in my judgment an 'adequate direction' for the use of the product. It is not to be used at all unless a physician directs it. To put more on the label would be to suggest it could be used without the direction of a physician which would be more apt to be false and misleading than the simple statement as used.

"The words 'nephritis, myocarditis and arteriosclerosis' are dictionary words which are commonly understood to mean certain types of kidney, heart or arterial diseases. The warning that the product should not be used in such cases appearing under the

word Important together with the statement, 'To be used as directed by physician,' is an 'adequate warning' sufficient to comply with the statute as to all except children, and is not false or misleading.

"As to the 'adequate warning against its use by children' I do not know how a more adequate warning could be given on a label than the statement 'not to be used by children.'

"The motion to dismiss is granted."

5. REBUTTAL EVIDENCE.

(a) Affidavit of Lewis A. Schinazi.

An affidavit was executed by Lewis A. Schinazi, an inspector of the Food and Drug Administration, in case No. 10266-HW, on November 3, 1949. The affidavit was obviously intended to rebut the allegations of the Clemens affidavit concerning the relabeling of the product after the criminal case [R. 94] and to create the inference that the labeling was merely a subterfuge. In his affidavit he alleged that he made a purchase on August 9, 1949, of a carton of methyl testosterone from Mr. Clemens, the defendant in action No. 10266-HW, at the place of business of defendant in that case; that the salesman asked him for his name and address, stating that he wished to inform him (the affiant) about new products in the field which might be of interest to him; that on November 2, 1949, he received through the mail from Vita-Pharmacals, Inc., the successor to El-O-Pathic Pharmacy, some documents, consisting of three circulars

attached as exhibits to his affidavit, one a price list and another a circular pertaining to a product called "Retarder" and a circular concerning an introductory offer on hormone products [R. 120-123].

(b) Affidavit of Albert H. Wells.

This affidavit was executed by Wells, a chemist with the Food and Drug Administration, and was obviously executed to rebut the contentions of the defendants that the relabeling was done in good faith and that the new label was intended by them to mean what it said (see Clemens Affidavit [R. 94-100]). This affidavit alleged the purchase of male hormone products on November 22, 1949, alleged a conversation with the salesman at the store of the defendant, Vita-Pharmacals, and another conversation on November 23, 1949, with a clerk in the store. This affidavit was filed November 23, 1949 [R. 131-136].

(c) Supplemental Affidavit of Robert S. Roe.

Robert S. Roe executed a Supplemental Affidavit December 1, 1949, alleging that during October and November of that year he conducted two investigations "to ascertain whether the labeling of the male hormone products distributed by Vita-Pharmacals Company, *et al.*, defendants in the above entitled proceedings, in fact caused purchasers to consult physicians before taking the drug" and attached to his affidavit were affidavits of individuals who had been contacted by inspectors under his supervision on that subject [R. 136-147].

Obviously this affidavit was for the single purpose to determine whether people who bought the product paid any attention to the label and, as we shall point out in our brief, was of the rankest type of hearsay and of no evidentiary value whatever.

(d) Affidavit of Walter F. McRae.

Mr. McRae was Acting Chief of the Los Angeles District, Food and Drug Administration. His affidavit was executed in rebuttal to the Supplemental Affidavit of Clemens, attaching cartons of Dr. Pierce's Favorite Prescription, Dr. Pierce's Golden Medical Discovery, Lydia E. Pinkham's Vegetable Compound, and Dr. Miles Nervine [R. 107-118].

Mr. McRae's affidavit alleged that a seizure action was pending in Pennsylvania against the Dr. Pierce remedies, that the Lydia E. Pinkham preparation is currently under investigation. There was attached to his affidavit an advertisement which he alleged appeared in the Los Angeles Times on January 22, 1950, purchased by the defendants, Vita-Pharmacals, Inc. Apparently the purpose of this inclusion was on the theory that the relabeling of the products was a subterfuge [R. 128]. This affidavit also attached a copy of a letter dated January 16, 1950, addressed to the California State Board of Pharmacy by the Director of Public Health of that state urging the Board to declare, among other things, that testosterone was a dangerous drug and should only be sold on prescrip-

tion. His affidavit further stated that commencing February 7, 1950, hearings would be held by the Board on the question. Apparently the purpose of including this letter was to create the inference that the Director of Public Health was of the same view as the Government. Mr. McRae's affidavit was sworn to January 27, 1950 [R. 126-131].

Under the stipulation as to the record in action No. 10266-HW, the Supplemental Affidavit of Robert S. Roe, above referred to [R. 136], the Affidavit of Wells, the Affidavit of McRae and the transcript of the evidence, including exhibits in the criminal cases, were made part of the record in this injunction action, subject to any objections as to relevancy and materiality [R. 150].

In the injunction action against the Hudson Products Company, No. 10391-HW, the above referred to Supplemental Affidavit of Roe, the Affidavit of McRae, and the transcript of the evidence, including exhibits in the criminal cases, were made part of the record subject to objections as to relevancy and materiality [R. 266].

It was further stipulated, however, in this action against Hudson Products Company that none of the evidence in the transcript pertaining to the alleged danger of using testosterone under certain circumstances was introduced as against Allen H. Parkinson, defendant in action No. 20642, Criminal, and there was no charge by the Government in that action that the warning statement on the labeling involved in that action which related to the product sold by him was inadequate [R. 266].

(e) Testimony of Dr. Elwyn Terrill.

This doctor was called on rebuttal to rebut the testimony of the defense witnesses to the effect that it was general practice, at least in the Los Angeles area, for general practitioners to prescribe testosterone when called upon to do so, without in any way submitting the patient to the elaborate tests mentioned by the Government witnesses. He testified at the criminal case and stated that he practiced in Los Angeles and in his practice prescribes testosterone occasionally in limited field and that he takes a very careful history on all patients and examines them completely before prescribing it [R. 925]. Among his circle of friends he knows that those precautionary measures are generally taken in the profession [R. 926]. He was asked the following:

“Q. Now, if I told you that a man of about 65 years called on each of the doctors whose names appear on the prescription pads that you have examined and told them that he wanted a refill of this bottle of Metandren Linguets, which is Defendants’ Exhibit K, 500 Metandren Linguets, and that each one of those doctors wrote a prescription for this gentleman without laying a hand upon him, would that change your opinion in any respect as to the ordinary course of practice pursued by doctors in this locality in the use of testosterone? A. I wouldn’t think that was general practice in my community, at least not among my associates.”

His office is in the same building in which the Food and Drug Administration offices are located [R. 928].

IV.

APPLICABLE REFERENCES TO THE LEGISLATIVE HISTORY PRECEDING THE ENACTMENT OF THE FOOD, DRUG AND COSMETIC ACT PERTINENT TO THE CONGRESSIONAL INTENT AS TO THE MEANING OF "ADEQUATE DIRECTIONS FOR USE" AND "ADEQUATE WARNINGS."

The references to the legislative history which follow in this portion of the Appendix have been taken in their entirety with one exception, from a book entitled "Federal Food, Drug and Cosmetic Act—A Statement of its Legislative Record" prepared by Charles Wesley Dunn of the New York Bar and published by G. E. Stechert & Company in 1938. This book compactly and in one volume gives the entire legislative record of the Act, including reports in the House and in the Senate and the debates and covers the five year journey of this Act through the Congress until its final enactment in 1938. For convenience the references in the footnotes to the portions of this book will be for example to "Dunn, page"

As introduced in the Senate in 1933,¹ Section 8 of S. 1944 provided that a drug should be deemed misbranded:

"(d) If it is not subject to the provisions of paragraph (i) of this section, and its labeling fails to bear complete and explicit directions for use: *Provided*, That the Secretary may by regulation exempt any drug from any requirement of this paragraph if he deems such requirement unnecessary for the protection of public health."

¹Dunn, p. 41.

That Bill died in the Senate Committee and was superseded by S. 2000, 73rd Congress, Second Session.²

At the Senate hearings on S. 1944, W. G. Campbell, then Commissioner of Food and Drugs, stated concerning subparagraph (d) of Section 8, above quoted, as follows:

*"Paragraph (d) is merely to require that directions for use be stated on drug labels, that paragraph (d), of course, should be read in connection with section 4(a), which refers to the use of drugs. It makes compulsory the use of a label."*³ (Emphasis added.)

Section 8 of S. 2000, 73rd Congress, provided that a drug should be deemed misbranded:⁴

"(d) If its labeling fails to bear, plainly and conspicuously, complete and explicit directions for use: *Provided*, That where any requirement of this paragraph, as applied to any drug, is not necessary for the protection of the public health, the Secretary shall promulgate regulations, as provided by section 22, exempting such drug from such requirement.

"(e) If its label fails to bear (1) such warnings as may be prescribed by regulations, as provided by section 22, against use in such pathological conditions or by children where its use is contraindicated and may be dangerous to health, or against unsafe dosage or methods of administration or application; and (2) the common or usual name of the drug, if any there be: *Provided*, That subdivision (2) of this paragraph shall not apply to drugs subject to paragraph (b) of section 4."

²Dunn, p. 50

³Dunn, pp. 37, 1083.

⁴Dunn, pp. 56-57.

That Bill died in committee and was superseded by S. 2800, 73rd Congress, Second Session.⁵

The superseding Bill—S. 2800—73rd Congress, Second Session, provided in Section 8 as follows:⁶

“(e) If its labeling fails to bear plainly and conspicuously (1) complete and explicit directions for use, and (2) such warnings in such manner and form as may be prescribed by regulations, as provided by section 22, against use in such pathological conditions or by children where its use is contraindicated and may be dangerous to health, or against unsafe dosage or methods of administration or application: *Provided*, That where any requirement of subdivision (1) of this paragraph, as applied to any drug, is not necessary for the protection of the public health, the Secretary shall promulgate regulations, as provided by section 22, exempting such drug from such requirement.”

The report in the Senate on S. 2800, 73rd Congress, stated as follows:⁷

“Paragraph (e) requires that the labeling of drugs bear complete and explicit directions for use. Such information is usually necessary to the proper administration or use of drugs, *but where it is not necessary* authorization is provided for exemption from any requirement of this paragraph through the operation of the Public Health Committee. (Emphasis added.)

⁵Dunn, p. 67.

⁶Dunn, p. 76.

⁷Dunn, p. 123.

"This paragraph also defines a drug as misbranded if its labeling fails to bear such warnings, as may be prescribed by regulations set up through the operation of the Public Health Committee under section 22, against use in such pathological conditions or by children where its use is contraindicated and may be dangerous to health, or against unsafe dosage or methods of administration or application. There are many valuable drugs which must be administered with great care. They are just as potent for harm as for good. The mere giving of directions for use may not avert tragedy resulting from likely misuse, *unless accompanied by positive warnings*. For example, a patient suffering from asthma may take a potassium iodide preparation for the relief of the paroxysms, but if he has an arrested case of tuberculosis the drug may quickly render it dangerously active. Or the last doses of a bottle of worm medicine given without shaking before each dose may be fatal to children because the potent principle settles out on standing." (Emphasis added.)

Senator Copeland, the author of the new Food and Drug law,⁸ offered his own statement regarding this Bill and what he conceded it to be.⁹

With reference to the subject of directions for use and warnings, he stated:¹⁰

"There are many very useful drugs which should be employed only with great care and discretion because in improper dosage or when administered to children or when the patient is suffering from certain

⁸Dunn, p. 37.

⁹Dunn, p. 159.

¹⁰Dunn, p. 162.

disease complications the effect of these drugs may be disastrous. *S. 2800 provides an effective safeguard against these dangers* which cannot be controlled under the present law. It requires that all drugs bear explicit directions for use and appropriate warnings against their consumption by children or in certain disease conditions where the use is contraindicated and may be dangerous to health.” (Emphasis added.)

With respect to Section 9(a) of S. 2800, which section dealt with false advertising, Mr. Campbell also stated:¹¹

“And let me stop just at this point to comment upon the criticism so extensively voiced by the patent-medicine interest that the purpose of this bill is to stop self-medication. This paragraph (a) of section 9 would certainly be unnecessary if it were not contemplated that self-medication will continue in the future as it has in the past. Physicians do not need such information; nor would they need but little of the information required by the succeeding paragraphs of this section. All of the provisions dealing with drugs, aside from those recognized in the official compendia, are directed towards safeguarding the consumer who is attempting to administer to himself. If this measure passes, self-medication will become infinitely more safe than it has ever been in the past.”

Senator Copeland also stated in presenting this Bill that:¹²

“There is no more common or mistaken criticism of this bill than that it denies the right of self-

¹¹Dunn, p. 1195.

¹²Dunn, pp. 89-90.

medication, or, as the objector usually put it, 'You can't take an aspirin tablet without a doctor's prescription.' Nothing could be further from the truth. The proposed law simply contributes to the safety of self-medication by preventing medicines from being sold as 'cures' unless they really are cures. It requires that drugs which have only palliative effect shall say as much on the label."

At the hearings before a subcommittee of the House committee on interstate and foreign commerce on S. 5, 74th Congress, First Session, Mr. Campbell also testified. He indicated that the purpose of the authority to exempt from the requirement of adequate directions was to eliminate the necessity of drugs or products to be used in compounding prescriptions—which is actually one of its applications under the regulations promulgated under Section 502 of the Act (21 U. S. C. 352)¹³—but he did not forecast any such extensive rules as those affecting drugs which the Food and Drug Administration regards as unsafe or inefficacious for use except under medical supervision.¹⁴

S. 5, as reported in the 74th Congress, with the Senate committee's substitute report, provided that a drug would be deemed to be misbranded if it were dangerous to health under the conditions of use prescribed in its labeling or advertising. The report stated in this regard:¹⁵

" * * There are no useful products which would be barred from the market under this provision, since labeling with proper directions for use*

¹³Regulations, Sec. 1.106, Title 21, Code of Federal Regulations (1949 Edition), p. 17.

¹⁴Dunn, p. 1235.

¹⁵Dunn, p. 483.

would remove any worth-while article from this ban. Under the present law, which contains no provision of this character, there have come on the market a number of dangerous drugs from the use of which many authenticated cases of death and impairment of health have been reported. So long as their labels bore no false or misleading statements, the public could not be protected.

“* * * *It is not intended that this provision should ban the sale of useful drugs of this kind when they are appropriately labeled.*” (Emphasis added.)

It would be presumed that if the committee had thought that certain essential drugs might be characterized as so unsafe that proper labeling could not be devised for them, it would at that point have said so, but no reference has been found in the history of later versions of S. 5 which would be indicative of such an understanding.

It is believed that it may be properly assumed that Section 502(f)(2) of the Act (21, U. S. C. 352(f)(2)) requiring warnings against possible misuse was regarded by the Congress and the committees as sufficient protection of consumers against misuse of the class of drugs which the Food and Drug Administration now contends must, under Regulation, Section 1.106, *supra*, bear the prescription legend. There are repeated statements and committee reports and by sponsors of the several bills that the purpose of the section was to guard against misuse of “potent” drugs.¹⁶

¹⁶S. Rep. 493, 73d Cong., 2d Sess., Dunn, p. 123.

Statement of W. G. Campbell in hearings before a subcommittee of the Senate Committee on Commerce on S. 5, 74th Cong., 1st Sess., Dunn, p. 1226.

Letter of the Secretary of Agriculture contained in a minority report on S. 5, S. Rep. 2139, 75th Cong., Dunn, p. 837.

Some of the earlier bills leading to the enactment of the present Food, Drug and Cosmetic Act provided that advertisements for certain named diseases “wherein self-medication may be especially dangerous” should be deemed false except when disseminated to the medical profession.¹⁷ No comparable provision is in the existing Act.

Senator Copeland, in a statement referring to such a provision in S. 5, recognized certain criticisms of the profession arising from a fear that an individual “would no longer be permitted to buy any favorite prescription *and to take it under the direction of the label*,” and he said “*Of course, that was not the intent of the proposed law.*”¹⁸ (Emphasis added.)

S. 2800, 73rd Congress, died on the Senate Calendar.¹⁹ Then S. 5, 74th Congress, First and Second Sessions, succeeded S. 2800, of which it was a revision.²⁰

Section 402 of that Bill provided that a drug should be deemed misbranded:²¹

“(f) If its labeling fails to bear plainly and conspicuously (1) complete and explicit directions for use, and (2) such warnings in such manner and form as may be prescribed by regulations, as provided by sections 701 and 703, against use in such pathological conditions or by children where its use is contradicted and may be dangerous to health, or against unsafe

¹⁷S. 1944, 73d Cong., 1st Sess., Sec. (c), Dunn, p. 42; S. 2000, Dunn, p. 58; S. 2800, Dunn, p. 77; S. 5, Dunn, p. 200.

¹⁸79th Congressional Record, part 1, 150.

¹⁹Dunn, p. 188.

²⁰Dunn, p. 189.

²¹Dunn, p. 197.

dosage or methods or duration of administration or application: *Provided*, That where any requirement of subdivision (1) of this paragraph, as applied to any drug, is not necessary for the protection of the public health, the Secretary shall promulgate regulations, as provided by sections 701 and 703, exempting such drug from such requirement.”

Certain amendments were made to S. 5 by the committee on commerce and the Bill, with the amendments, was reported in the Senate.²²

Section 402 of the amended Bill provided in part as follows:²³

“(f) If its labeling fails to bear plainly and conspicuously (1) complete and *adequate* directions for use, and (2) such warnings in such manner and form as may be prescribed by regulations, as provided by sections 701 and 703, against use in such pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application: *Provided*, That where any requirement of subdivision (1) of this paragraph, as applied to any drug is not necessary for the protection of the public health, the Secretary shall promulgate regulations, as provided by sections 701 and 703, exempting such drug from such requirement.”

The report in the Senate of this Bill provided with respect to subdivision (f) as follows:²⁴

“Paragraph (f) requires that the labeling of drugs bear complete and adequate directions for use. Such

²²Dunn, p. 213.

²³Dunn, p. 220.

²⁴Dunn, p. 254.

information is usually necessary to the proper administration or use of drugs, *but where it is not necessary* authorization is provided for exemption from any requirement of this paragraph through the operation of the Public Health Committee. (Emphasis added.)

“This paragraph also defines a drug as misbranded if its labeling fails to bear such warnings, as may be prescribed by regulations set up through the operation of the Public Health Committee, against use in such pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application. There are many valuable drugs which must be administered with great care. They are just as potent for harm as for good. The mere giving of directions for use may not avert tragedy. For example, a patient suffering from asthma may take a potassium iodide preparation for the relief of the paroxysms, but if he has an arrested case of tuberculosis the drug may quickly render it dangerous active. Or the last doses of a bottle of worm medicine given without shaking before each dose may be fatal to children because the potent principle settles out on standing. *Warnings against probable misuse are therefore essential to public-health protection.*” (Emphasis added.)

A substitute report on S. 5, 74th Congress, was submitted in which was stated²⁵ substantially the same as that contained in the quotation immediately preceding.

During the debate in the Senate on S. 5, 74th Congress, an amendment was offered to strike out “prescribed by

²⁵Dunn, p. 484.

regulations, as provided by Sections 701 and 703” and insert “adequate” so as to read:²⁶

“(g) If its labeling fails to bear plainly and conspicuously (1) complete and adequate directions for use, and (2) such warnings in such manner and form as may be adequate against use in such pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application: *Provided*, That where any requirement of subdivision (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations, as provided by sections 701 and 703, exempting such drug from such requirement.”

This amendment was agreed to by the Senate.²⁷

This Bill as reported in the House, revised completely S. 5 and, as reported in the House, provided in part that a drug should be deemed misbranded:²⁸

“(g) If its labeling fails to bear plainly and conspicuously (1) adequate directions for use, or (2) such warnings, in such manner and form, as are required by regulations prescribed by the Secretary, against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application: *Provided*, That where any requirement of subdivision (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall

²⁶Dunn, p. 499.

²⁷Dunn, p. 499.

²⁸Dunn, p. 538.

promulgate regulations exempting such drug or device from such requirement.”

The report in the House of S. 5, 74th Congress, stated with reference to the section under consideration as follows:²⁹

“Section 402(g): In this paragraph as it passed the Senate a drug or device is deemed to be misbranded unless its labeling bears such warnings in such form and manner as may be adequate. The committee changed this to require such warnings as are required by regulations prescribed by the Secretary; its reason for so doing being that it believed that the requirement of the Senate bill was so vague that it might be held to be invalid. Certainly the manufacturers of drugs and devices would have had grave difficulty in telling what warnings would have been ‘adequate’ on the labeling of many products.”

The Senate agreed to the House amendment.³⁰

S. 5 of the 74th Congress died in the House.³¹

S. 5, 75th Congress, as introduced in the Senate, provided that a drug should be deemed misbranded:³²

“(g) If its labeling fails to bear plainly and conspicuously (1) adequate directions for use, or (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application: *Pro-*

²⁹Dunn, p. 555.

³⁰Dunn, p. 605.

³¹Dunn, p. 633.

³²Dunn, p. 648.

vided, That where any requirement of subdivision (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement."

The report in the Senate stated that with respect to this Bill, that among other things it:³³

"Requires adequate directions for use of drugs and devices and appropriate warnings against their probable misuse through overdosage, or by children, or in disease conditions where they may be dangerous."

As recommended by the House subcommittee, Section 502(f) of S. 5, 75th Congress, reads as follows:³⁴

"(f) Unless its labeling bears (1) adequate directions for use; and (2) such warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as the Secretary finds necessary for the protection of users and by regulations prescribes: *Provided*, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement."

S. 5, 75th Congress, as reported in the House, followed the Bill as recommended by the House subcommittee, so far as Section 502(f) above quoted is concerned.³⁵

³³Dunn, p. 680.

³⁴Dunn, p. 764.

³⁵Dunn, p. 805.

The report in the House of S. 5, 75th Congress, stated that one of the principal respects in which the Bill differs from the present law is that:³⁶

“Potent drugs liable to be misused must bear label warnings against probable misuse.”

This same report also states as follows:³⁷

“Other provisions of section 502 are designed to require the labeling of drugs and devices with information essential to the consumer. *The bill is not intended to restrict in any way the availability of drugs for self-medication. On the contrary, it is intended to make self-medication safer and more effective. For this purpose provisions are included in this section requiring the appropriate labeling of habit-forming drugs, requiring that labels bear adequate directions for use and warnings against probable misuse, and setting up appropriate provisions for deteriorating drugs.*” (Emphasis added.)

The statement of the Managers on the part of the House³⁸ was read and stated the important changes from the House amendment, one of them being with regard to warnings.³⁹

“*Warnings against misuse of drugs and devices.*— Under the House amendment a drug or device is considered misbranded unless its labeling bears such warnings against use in pathological conditions or by

³⁶Dunn, p. 816.

³⁷Dunn, p. 822.

³⁸Dunn, p. 992.

³⁹Dunn, p. 995.

children where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as the Secretary finds necessary for the protection of users and by regulations prescribes. Under the conference agreement a drug or device is considered misbranded unless its labeling bears such adequate warnings in the cases specified in the House amendment as are necessary for the protection of users.”

With respect to the subsection under consideration and during the discussion in the House in which the House agreed to the conference report as to S. 5, 75th Congress, Senator Lea, one of the principal proponents in the Senate of this Bill, stated in part as follows:⁴⁰

“The conferees also agreed upon a provision requiring adequate warnings upon the label against use in certain pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or duration of use. *The substance of the change as agreed to by the conference is that the warning must be ‘adequate’ instead of being prescribed by regulations of the Secretary. The Secretary, however, can prescribe exemptions to those regulations on the ground of impracticability.*” (Emphasis added.)

The Bill as introduced in the Senate, S. 5, 74th Congress,⁴¹ quoted *supra* (page 69 of this Appendix) was

⁴⁰Dunn, p. 999.

⁴¹Dunn, p. 197.

also referred to by Mr. Campbell during Senate hearings on this Bill. With reference thereto Mr. Campbell stated.⁴²

“Suggestion has been made that paragraph (f) be deleted. This proposal is advanced in the understanding that paragraph 401(a)(1) makes paragraph (f) unnecessary; 401(a)(1) deals with products which are of a toxic or poisonous character and with directions for their use. Paragraph (f) relates more to the precautions which should be expressed against the misuse of potent drugs. This is particularly true in the sale of powerful sedative drugs, particularly those which affect the heart. The consumer will ordinarily be without knowledge of the consequence of a too frequently repeated use and might be induced, in fact frequently is induced, through securing partial relief from the first dose, to repeat or increase the dose, to his very definite injury. *A precautionary statement against misuse in this manner should be carried in a conspicuous portion of the labeling of such products.*” (Emphasis added.)

In a letter from the Secretary of Agriculture to the Senate November 25, 1937, the Secretary requested that in order “to protect the public from drugs which, like the ‘elixir,’ are dangerous because of their inherent toxicity, it is the Department’s recommendation that legislation be enacted to provide at least the following:⁴³

“3. Requirement that drug labels bear appropriate directions for use and warnings against probable misuse. Much injury results from insufficient directions

⁴²Dunn, p. 1226.

⁴³Dunn, p. 1326.

and from lack of warning against overdosage, or administration to children, or use in disease conditions where the drug is dangerous, or possibility of drug addiction.”

81st Congress
2d Session

S. 3852

A BILL

To amend section 503(b) of the Federal Food, Drug, and
Cosmetic Act.

By Mr. Humphrey

June 29 (legislative day, June 7), 1950

Read twice and referred to the Committee on Labor and
Public Welfare

81st Congress
2d Session

S. 3852

IN THE SENATE OF THE UNITED STATES

June 29 (legislative day, June 7), 1950

Mr. Humphrey introduced the following bill; which was
read twice and referred to the Committee on Labor
and Public Welfare

A BILL

To amend section 503(b) of the Federal Food, Drug, and
Cosmetic Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assem-

bled, That subsection (b) of section 503 of the Federal Food, Drug, and Cosmetic Act, as amended, is amended to read as follows:

“(b) A drug dispensed by filling or refilling a written or oral prescription of a physician, dentist, or veterinarian licensed by law to administer such drug shall be exempt from the requirements of section 502, except paragraphs (a), (i) (2) and (3), (k), and (l), and the packaging requirements of paragraphs (g) and (h), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription, or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail or otherwise without examination of the patient. If the drug is intended for use by man and—

‘(1) is a habit-forming drug subject to the regulations prescribed under section 502(d), or

‘(2) has been found by the Administrator, after investigation and opportunity for public hearing, to be unsafe or ineffective for use without the professional diagnosis or supervision of a physician or dentist, or

‘(3) if an effective application under section 505 limits it to use under the professional supervision of a physician or dentist,

such exemption shall apply only if such drug is dispensed upon a written prescription of a physician or dentist licensed by law to administer such drug or upon an oral prescription of such physician or dentist which

the prescriber agrees to confirm in writing within seventy-two hours, or is dispensed by refilling a prescription if such refilling is authorized by the prescriber in the original prescription or by oral order and agreement of the prescriber to confirm such order in writing within seventy-two hours.

“The Administrator may by regulation remove drugs subject to section 502(d) from the provision of this subsection when such requirements are not necessary for the protection of the public health.

“A drug which is subject to clause (1), (2), or (3) of this subsection shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement ‘Caution: Federal law prohibits sale or dispensing without prescription’.

“The act of dispensing a drug contrary to the provisions of this subsection shall be deemed to be an act which results in the drug’s being misbranded while held for sale.”

United States Court of Appeals

FOR THE NINTH CIRCUIT

LEO LICHTENSTEIN, LIBBIE LICHTENSTEIN and
BRYON J. LICHTENSTEIN, individually and trad-
ing as Harlich Manufacturing Company and Loomis
Manufacturing Company,

Petitioners,

vs.

FEDERAL TRADE COMMISSION,

Respondent.

Petition for Rehearing

PETITION TO REVIEW AN ORDER OF
THE FEDERAL TRADE COMMISSION

F. W. James,
9448 Drake Ave.,
Evanston, Ill.
Attorney for Petitioners.

FILED

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FEB 25 1952

United States Court of Appeals

FOR THE NINTH CIRCUIT

No. 12,666

LEO LICHTENSTEIN, LIBBIE LICHTENSTEIN and
BRYON J. LICHTENSTEIN, individually and trad-
ing as Harlich Manufacturing Company and Loomis
Manufacturing Company, Petitioners,

vs.

FEDERAL TRADE COMMISSION, Respondent.

PETITION TO REVIEW AN ORDER OF THE FEDERAL TRADE COMMISSION

Come now the above named petitioners and respectfully
petition the Court for a rehearing hereof for the following
reasons.

Petition for Rehearing

I.

One of petitioners points is that the only acts and prac-
tices within the jurisdiction of the Federal Trade Commission
are acts and practices which are either unfair to competitors,
consumers, or both. To sustain this proposition the petition-
ers as part of their argument on this point cited the testimony
of the late Commissioner Davis given before the committee.
This testimony showed clearly that the only purpose of the
Wheeler Lea Amendment was to give the commission ad-
ditional jurisdiction to protect the consumer. On this point,
the opinion herein refers to the history of the act and in a
footnote sets out some of the comments made by the author
of the amendment, Mr. Lea. In the footnote it is said:

“Indeed, the principle of the act is carried further to
protect the consumer as well as the competitor. In
practice the main feature will be to relieve the com-
mission of this burden, but we go further and afford

a protection to the consumers of the country that they have not heretofore enjoyed."

And Senator Wheeler as set out in the same footnote stated:

"This amendment makes the consumer who may be injured by an unfair trade practice of equal concern before the law with the merchant injured by the unfair methods of a dishonest competitor."

The review of the history of Section 5 (a) substantiates petitioner's contention that the only acts and practices which are within the jurisdiction of the Federal Trade Commission are acts and practices which are either unfair to competitors, consumers or both.

It is self-evident and the commission admits that the acts and practices complained of in this proceedings are not unfair to competitors or consumers. Therefore, petitioners conduct is not within the purview of the Federal Trade Commission Act and because of this the order issued herein should be set aside.

II.

Neither the case of Charles A. Brewer and Sons vs. Federal Trade Commission, 158 F. 2d 74, nor the Globe Cardboard Novelty Company case were decided upon the basis that the practices herein involved were unfair to competitors or consumers. Both cases were predicated upon the erroneous assumption that the intrastate use of punch boards is within the Federal Trade Commission Act. It is fundamental as both opinions are predicated upon this assumption that if the assumption is erroneous then the decisions are also erroneous. The assumption is without question erroneous because the Supreme Court has so held. In other words, these two cases have overruled the Supreme Court.

III.

It is the petitioners contention that what may have been said concerning Public Law 906, 81st Cong., 2d Sess., ap-

proved January 2, 1951, forbidding the transportation of slot machines has no bearing upon the power given to the Federal Trade Commission. Had the Bunte case been taken into consideration at the time, undoubtedly those remarks would not have been made. What the Supreme Court says certainly should have more authority than what the 6th Circuit says. When the Supreme Court construed the Federal Trade Commission Act remarks in a congressional report or statement by members of Congress cannot override the Supreme Courts ruling. Petitioners position is that the saving clause of the slot machine act must be interputed in the light of the holding by the Supreme Court in the Bunte case.

IV.

Petitioners failed to clearly present to this court their contention concerning the public interest. The opinion herein states:

“Petitioner further urges that the prevention of the use of its gambling devices in the sale of merchandise to the ultimate consumer is not in the public interest.”

This is not our contention at all. Our contention is that it is not to the public interest as that expression is used in the Federal Trade Commission Act to issue a cease and desist order against petitioners shipping punch boards in interstate commerce. Our reasons are as follows: The stopping of the interstate shipment of punch boards will not in any degree minimize the distribution of merchandise by lotteries. Because punch boards are not the only devices used for this purpose so that if the use of all punch boards is eliminated the distribution of merchandise by lotteries would go on unabated. Furthermore, practically every state in the Union has some form of a punch board or push card factory, the local factories furnish all the punch boards needed. It seems to the petitioners that it is obvious that the public are not interested in the Federal Government spending all the money it is spending in proceedings of this type when the only result is that petitioners are stopped from shipping of punch

boards in interstate commerce which has absolutely no effect on the use of lotteries to distribute merchandise.

V.

Petitioner's wish to again press their point that the order issued herein is broader than the complaint, therefore the order must be modified in such manner as will bring it within the limited allegations of the complaint. On this point, the Supreme Court has held, in the case of Federal Trade Commission vs Gratz, 253 U. S. 421, 427 40 S ct, 572, 574, 64 L ed 993, "The things which may be prohibited is the method of competition specified in the complaint. Such an order should *follow the complaint*; otherwise, it is improvident, and, when challenged will be annulled by the court."

The complaint alleges that:

"Petitioners supplies to, and places in the hands of persons, firms and corporations the means of and instrumentalities for, engaging in unfair acts and the practices within the intent and meaning of the Federal Trade Commission Act." (Rec. 22)

Under the principle of law set out by the Supreme Court in the Gratz case, supra; the order should be modified to read as follows:

The petitioners are ordered to cease and desist from placing in the hands of persons, firms and corporations the means of and instrumentalities for engaging in unfair acts and practices within the intent and meaning of the Federal Trade Commission Act.

Respectfully submitted,

F. W. JAMES,
Attorney for petitioners

CERTIFICATE

Comes now the undersigned attorney for petitioners herein and hereby certifies that in his judgment this Petition is well founded and is not interposed for delay.

F. W. JAMES

